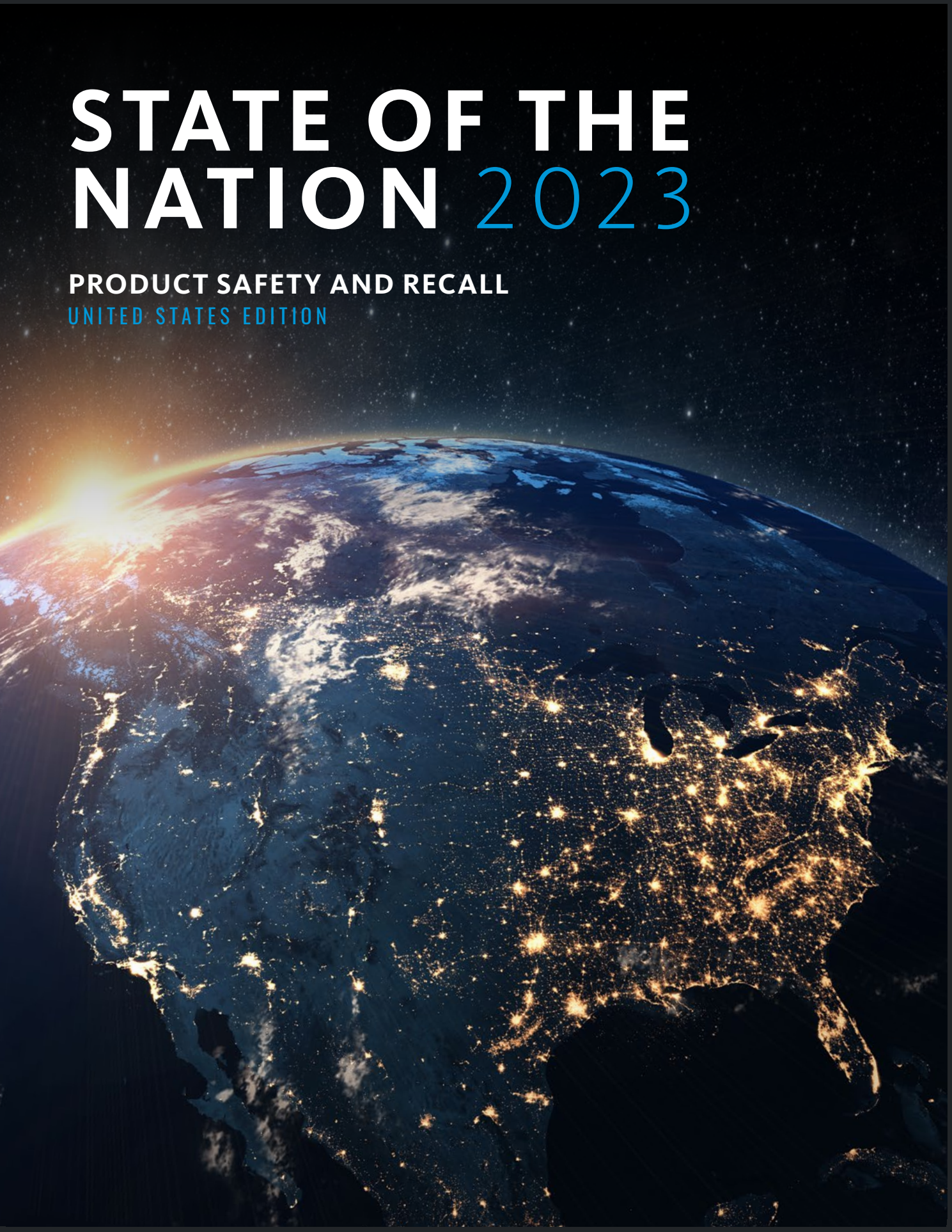
STATE OF THE NATION 2023

PRODUCT SAFETY AND RECALL

UNITED STATES EDITION



DATA, TRENDS & PREDICTIONS **FOR US INDUSTRIES**

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The Sedgwick brand protection Recall Index is a leading resource for manufacturers, suppliers and retailers looking for an unbiased, informed perspective on past, present and future product safety trends and recall data. It reviews five product categories: Automotive, Consumer Products, Food and Drink, Pharmaceuticals and Medical Devices.

The report collects and analyzes data from the U.S. Consumer Product Safety Commission (CPSC), the U.S. Food and Drug Administration (FDA), the U.S. National Highway Traffic Safety Administration (NHTSA) and the U.S. Department of Agriculture (USDA) to give businesses valuable insights for protecting their brands against risks to their operations and their reputations.

This edition brings you recall data from the fourth quarter of 2022, October 1 – December 31, along with a look at all of 2022 and an early glance at January 2023 data. As we shared last quarter, by Q3, the U.S. had broken a 20-year record for the number of products recalled annually with a whole quarter still to go. The year ended with 1.48 billion products recalled across five industry sectors: automotive, consumer goods, food and drink, pharmaceuticals and medical devices. That is 23.4% higher than the previous record of 1.20 billion set in 2018 and 46.4% more than the total for 2021.

The overall rise was driven primarily by increases in recall size for the food and pharmaceutical industries. Both sectors registered over ten-year highs in the total number of annual units recalled . In the food sector, the total number of units recalled in 2022 was 416.9 million, which is 24.9% more than the next highest amount recorded in 2016 (333.9M). In the pharmaceutical sector, the total number of units recalled in 2022 was 567.3 million, which is 39.3% more than the next highest amount recorded in 2018 (407.4M).

In addition to insights on recall data trends, Sedgwick's brand protection Recall Index provides unrivalled analysis and opinion on the key issues that business leaders and regulators should be watching for. We partner with leading law firms and insurance companies to offer exclusive perspectives that help companies across industries to mitigate recall risk and protect their bottom-line.

One of the areas that we are closely monitoring is the impact of the Consolidated Appropriations Act, 2023 (H.R. 2617) that was signed in December 2022. This omnibus appropriations bill included a series of reforms relevant to the FDA including the Food and Drug Omnibus Reform Act of 2022 (FDORA), the Modernization of Cosmetics Regulation Act of 2022 (MOCRA) and mandates for medical device manufacturers to reduce cyber threats. All of these acts have numerous new obligations for manufacturers and other stakeholders around issues such as marketing, clinical trials and the FDA's authority.

Whether you read this Index report cover to cover, or just hone in on the sections that matter most to you, we are confident you will learn something new that is relevant to your business or your industry.

One final note, this edition of the Recall Index focuses on U.S. recall data and regulatory developments. If your business also operates outside the United States, we encourage you to read our European Edition. Like this report, it shares recall data from regulatory agencies and offers expert analysis on product safety and regulatory changes, but from the perspective of companies operating in the UK and the European Union.

European edition available here: click here

If you would like more information about what we have observed in recent quarters, you can find previous editions of the Recall Index below:

Q3 2022 U.S. Recall Index: click here
Q2 2022 U.S. Recall Index: click here
Q1 2022 U.S. Recall Index: click here
Q4 2021 U.S. Recall Index: click here

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State of the nation 2023

SUMMARY

Despite the U.S. still being under the ongoing COVID-19 public health emergency, many companies were trying to get back to business as normal in 2022. However, there were still lingering supply chain issues, which were compounded by domestic political concerns and global geopolitical issues including the war in Ukraine.

Those challenges didn't seem to slow down regulators when it came to protecting consumers, as seen by the record-setting year for the number of units recalled. The pace for the year was really set in the first quarter. There were 913.8 million total units recalled across all five sectors in the first quarter alone.

To put that number in perspective, the next highest quarterly total was recorded in Q1 2018 with 567.9 million units. Q1 2022 saw the most defective pharmaceutical units to be recalled in a single quarter (435.3 million) over the past 10 years, and the third-highest number of medical devices (314.8 million) in the same time period. Thankfully, the rate of recalled units diminished as the year progressed. There were only 75 million units recalled in Q2, with 227.8 million and 262.2 million recalled in Q3 and Q4 respectively.

A recall of infant formula that resulted in two deaths was the biggest story of the year in terms of food recalls. While it was not the largest recall by volume, it had lasting repercussions on the supply of formula for months and led to calls for reform in the industry and within the FDA itself. The bacteria that led to the recall of 14.89 million units of infant formula and the closing of major production facilities had been reported on eight separate instances between 2019-2022 at one of the facilities, but no further action seemed to have been taken by the FDA.

In September the FDA released an internal report on its response to the infant formula crisis. In the wake of the recall, FDA Commissioner Robert Califf also announced an independent investigation into its entire Human Foods Program (HFP), the findings of which were released in December.

The food industry faced another crisis when a major recall of peanut butter products impacted 21 different food items and led to the recall of 12.2 million units. However, the widespread damage was not as great as it was with the infant formula event.

In Q4, the FDA took two actions that would seemingly help address future food safety issues. One was the release of an independent review of the HFP. This was announced in July in the wake of the infant formula recall. The expert panel recommended a new organizational structure and more resources, among other changes. The agency also released the Food Traceability Final Rule, which is designed to help supply chain partners and regulators trace food products more efficiently and effectively if safety issues are suspected.

The Consumer Products Safety Commission (CPSC) and the Federal Trade Commission (FTC) were also more aggressive and more public in their enforcement actions. Having regulators step up monitoring and enforcement raises risks for companies from legal, compliance and reputational perspectives.

Another change that came about in 2022 is that agencies (such as the U.S. Food and Drug Administration) have held onto tools authorized at the start of the pandemic such as remote regulatory assessments (RRAs), including electronic records requests. These types of assessments have pros and cons for companies but could mean the need to update record-keeping to be able to respond quickly to any document requests and potentially an increase in the number of inspections, since regulators do not have to travel from site to site.

Here are some of the sector highlights for the year:

Automotive

The National Highway Traffic Safety Administration (NHTSA) had a 12.6% decrease in automotive recalls for 2022 compared to 2021. Year-over-year, the industry finished with 3.5 million fewer units recalled in 2022 compared to 2021 and the fewest units recalled annually in the last six years.

Autonomous vehicles (AVs) and electric vehicles (EVs) continued to hold the attention of regulators and stakeholders across the automotive industry. Bloomberg predicted that once countries hit a metric of 5% of new car sales being powered only by electricity, mass adoption of EVs is sure to follow. In the third quarter 2022, the U.S. total market share for EVs passed 6%.

In an effort to boost EV adoption, the Biden Administration has taken several steps to create a nationwide EV charging network. One of the biggest proposed changes to help boost EV production and adoption is around the Renewable Fuel Standards (RFS) program. The EPA has suggested making EV manufacturers the sole entity able to generate and sell eRINs, a new category of Renewable Identification Numbers (RINs), which are RFS credits that can be traded, bought and sold.

Other green news that will have a big impact on the automotive industry is the final Corporate Average Fuel Economy (CAFE) criteria for fuel economy. In March, NHTSA finalized significant increases to civil penalties setting automakers up for fines of millions of dollars for failure to comply.

Research released in Q4 also highlighted concerns about cybersecurity threats due to the way some manufacturers' apps share vehicle and owner information with third-party systems. The risk is that hackers could remotely unlock doors, start the engine or access personal data from infotainment systems.

For a more in-depth analysis of the automotive industry in 2022, and our predictions for the remainder of 2023, click here.

Consumer products

The Consumer Product Safety Commission (CPSC) hit a six-year high in 2022 for the number of product recalls in a single year with 286 events. That is up 31.2% compared to 2021. In terms of units recalled, though, the 2022 numbers were much lower. There were 23.4 million items recalled in 2022 versus 42.8 million total units in 2021. It is worth noting that 2021 was a particularly active year in terms of volume. The 2022 numbers are in line with annual totals from 2018-2020 in terms of both total units and average recall size.

One factor that may impact consumer product recalls as we progress in 2023 are the recent layoffs across the tech sector for both product manufacturers and major online distributors. These could affect product quality as well as oversight of the safety of products sold online. It is unclear if these cuts will influence the federal government's efforts to encourage more American manufacturing and investment in semiconductor chips to provide some relief for the ongoing product shortages.

The CPSC took a more aggressive enforcement stance in 2022, making it clear that companies needed to report any safety issues promptly or risk legal actions and steep fines. That approach is likely to continue in the new year. The Commission kicked off 2023 by announcing that a major exercise equipment brand had agreed to pay a $19,065,000 civil penalty.

Children's safety remained a top priority for American regulators with both the federal Safe Sleep for Babies Act of 2021 and the CPSC's Safety Standard for Infant Sleep Products going into effect.

Regulators have also been taking action on both a state and federal level regarding perfluoroalkyl and polyfluoroalkyl substances (PFAS). Inconsistent regulation among states and the federal government creates vulnerabilities for companies trying to comply with a patchwork of evolving rules. It also allows opportunities for plaintiffs' lawyers who are filing claims, alleging that companies didn't disclose the presence of PFAS (a dangerous chemical) in a product or its packaging, or that claims that products are "safe" are false advertising if they contain PFAS.

Like the CPSC, the Federal Trade Commission (FTC) has been increasing its monitoring and enforcement. It has announced proposed changes to its Green Guides to ensure eco-claims companies make in their marketing and advertising are lawful. It is also pursuing civil penalties against companies who violate the Made in the USA Rule and filed charges against three name-brand corporations to promote consumers' "right to repair."

For a more in-depth analysis of the consumer product industry in 2022, and our predictions for the remainder of 2023, click here.

Food and drink

The total number of units involved in FDA food recalls in 2022 was 700.6% higher than the previous year. In 2021 there were a total of 52.1 million units recalled by the FDA and the average recall size of 125,796 units. In 2022, those numbers grew to a total of 416.9 million units recalled for the year and an average recall size of 985,658 units.

The FDA announced a proposed rule that would update the criteria for including the claim "healthy" on food packaging in Q3 2022. The agency said the change would align the definition of the "healthy" claim with current nutrition science, the changes to the Nutrition Facts label and current Dietary Guidelines for Americans.

The agency also issued the Food Traceability Final Rule, a critical part of the FDA's New Era of Smarter Food Safety Blueprint that implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA). The rule is designed to improve the availability of information needed for effective and efficient tracing of foods and food products throughout the supply chain. The major food recalls this year, including the infant formula event, show the need for better information sharing.

Trends with the USDA data are very different than those seen with the FDA numbers. Annual totals for recalls year-over-year are almost identical between 2021 and 2022, with 47 and 46 events respectively. However, there was an 87.0% drop in the number of pounds recalled, with 13.35 million in 2021 and only 1.73 million in 2022.

For a more in-depth analysis of the food and drink industry in 2022, and our predictions for the remainder of 2023, click here.

Pharmaceuticals

With 567.3 million units recalled, 2022 saw the highest volume of pharmaceutical recalls in over ten years. There was a 114.4% increase compared to the 264.6 million units recalled in 2021. High totals in Q1 and Q3 made up for Q4 2022 which experienced the fewest number of pharmaceutical units recalled since Q4 2017.

In terms of recall events, there were 363 for all of 2022, up 32.5% compared to 2021, but roughly in line with annual totals in 2017-2020.

After more than a year without a permanent commissioner, Dr. Robert Califf was appointed to head the FDA in February 2022. Predictions that he would take a tough stance on regulating tobacco and tobacco products are holding up to be true. In Q2, the FDA increased its enforcement for cannabis and nicotine and issued its first warning letters for products containing delta-8 tetrahydrocannabinol (delta-8 THC), a psychoactive substance found in cannabis.

The agency also took aggressive action in banning the sale of one e-cigarette manufacturer's products and proposing rules to ban non-tobacco flavors including menthol in cigars and cigarettes. It also continued to pursue limitations on e-cigarettes and vaping products, despite suffering some legal setbacks in its efforts to regulate the marketing of these products.

In August, the agency delivered what appears to be its first warning letter to an online retail fulfillment company for shipping over-the-counter (OTC) medications without FDA approval. In the past, the agency has concentrated on marketers and more traditional retailers and manufacturers.

The biggest changes for the FDA came with the signing of the Consolidated Appropriations Act, 2023 (H.R. 2617) in December 2022. This omnibus appropriations bill included a series of reforms relevant to the pharmaceutical industry including the Food and Drug Omnibus Reform Act of 2022 (FDORA) and the Modernization of Cosmetics Regulation Act of 2022 (MOCRA). Both of these acts have numerous new obligations for manufacturers and other stakeholders around issues such as marketing, clinical trials and the FDA's authority.

In December the Federal Trade Commission (FTC) released its "Health Products Compliance Guidance," which means more adjustments for the industry. This is the first update in 25 years, and the guidelines now apply to not only dietary supplements but also anything deemed a "health product," which can include foods, OTC drugs, homeopathic products, health equipment, diagnostic tests and health apps.

For a more in-depth analysis of the pharmaceutical industry in 2022, and our predictions for the remainder of 2023, click here.

Medical devices

It seemed that 2022 would be a record year for medical device recalls. There were 314.8 million units recalled in Q1. Thankfully, that pace slowed down and Q2 was the lowest quarter by unit since Q1 2017. Overall, the number of units impacted for the year decreased from 602.5 million in 2021 to 438.4 million in 2022. This 27.2% drop may seem significant, but it really shows how much volume there was in 2021. The totals for 2022 are on par with total units for 2018-2020.

After years of discussion, the FDA published a proposed rule in February 2022 to synchronize U.S. medical device manufacturing standards with those of other nations. The change should make it easier for international medical device companies, though there are concerns that the transition timeline for the new requirements is too short, especially for smaller companies.

As medical devices become more digitally connected, the FDA issued its draft guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," in April 2022. The document provides detailed guidelines for manufacturers on steps they should take to reduce cybersecurity threats that arise from rapid advances in technology and the increased use of personal and interconnected medical devices.

The Consolidated Appropriations Act that was signed in December 2022 added more regulations for device manufacturers around reducing cyber threats. They will be required to submit plans for monitoring, identifying and addressing cybersecurity vulnerability once products are on the market. Previously, while the FDA had made recommendations regarding the need for device manufacturers to mitigate cybersecurity risk, there were no enforceable rules.

For a more in-depth analysis of the medical device industry in 2022, and our predictions for the remainder of 2023, click here.

AUTOMOTIVE

In the third quarter of 2022, the U.S. total market share for electric vehicles (EVs) passed 6%. This is a significant milestone because Bloomberg predicts that mass EV adoption is sure to follow once a country hits the 5% tipping point of new car sales being powered only by electricity.

One thing that could help boost EV adoption and production is the Environmental Protection Agency's (EPA's) proposed changes to the Renewable Fuel Standards (RFS) program. The EPA has suggested making EV manufacturers the sole entity able to generate and sell eRINs, a new category of Renewable Identification Numbers (RINs), or RFS credits. The agency suggests that giving automakers this benefit could help drive the growth of the EV market and possibly push vehicle prices down for consumers.

The agency also announced changes to the New Chemicals Program under the Toxic Substances Control Act (TSCA). The goal is to streamline the way the agency assesses risk and applies mitigation measures for new chemicals with applications in batteries, EVs, semiconductors and renewable energy generation. This could be another step toward spurring the EV market, as well as other green technologies.

While the move to EVs is being hailed as a great environmental advancement, other new technology is proving problematic. There is rising concern about cybersecurity threats from the way some manufacturers' apps share vehicle and owner information with third-party systems. The risk is that hackers could remotely unlock doors, start the engine or access personal data from infotainment systems.

> *"California became the first U.S. state to issue a phase-out of gas-powered vehicles, with the sale of these types of cars banned starting in 2035. At least 15 other states have backed California's zero-emission standards, with several moving towards adopting them."*

> *"AlixPartners predict that manufacturers will have to rely on their suppliers to drive 25% to 50% of the improvements needed to reduce emissions, with the majority of greenhouse gases being emitted by indirect sources."*

Proposed changes to the Renewable Fuel Standards are a boon to the EV market

In December 2022, the Environmental Protection Agency (EPA) published its proposed rule for the Renewable Fuel Standard (RFS) program for 2023-2025. Under the RFS program, refiners or importers of gasoline or diesel fuel must blend renewable fuels into transportation fuel or obtain credits, known as Renewable Identification Numbers (RINs), to comply with an EPA-specified Renewable Volume Obligation (RVO).

Historically, the EPA has considered renewable fuels that can earn RINs to be cellulosic biofuel, advanced biofuel, total renewable fuel, and biomass-based diesel. Under the draft regulation, the agency is also including electricity made from renewable biomass that is used for transportation fuel to charge EVs under a new category called eRINs.

Unlike the model the EPA has in place for renewable natural gas (RNG) where any party in the RNG generation/disposition chain can generate RINs, the agency has proposed that light-duty EV original equipment manufacturers (OEMs) be the sole party that can generate eRINs.

The EPA says this one-party approach will minimize program complexity and streamline enforceability. It also notes that OEMs are directly invested in the growth of EVs, so are uniquely positioned. The agency also suggests that eRIN revenue would allow OEMs to lower the purchase price of EVs which would increase their sales and lead to a greater number on the road and more renewable fuel used in transportation.

Under the draft rule, OEMs would be empowered to determine the renewable electricity consumption based on the size of their EV fleet (both new and in-use vehicles) and information regarding the electricity consumption of those vehicles.

EV manufacturers would be required to demonstrate that a vehicle's charging was completed with renewable electricity produced from a qualifying renewable source, currently certain forms of biogas. After that, OEMs would be permitted to enter into a RIN generation agreement with a renewable electricity generator for the exclusive right to generate eRINs. Facilities would only be permitted to enter into RIN generation agreements with a single OEM.

The EPA's public comment period for the new rule closed on February 10, 2023. The proposal stated EV manufacturers would be permitted to produce eRIN credits beginning in 2024.

Suppliers' role in meeting automakers' green commitments

Regulators around the world have rolled out timelines for stopping the sale of gasoline-powered cars. The European Parliament and European Council signed an agreement in October 2022 that would ensure all new cars and vans registered in Europe will be zero-emission by 2035. In the U.S., the Biden Administration launched a plan in August 2021 to make half of all new U.S. vehicles electric in 2030, though that is a goal, not a regulation.

States are being more aggressive. In August 2022, California became the first U.S. state to issue a phase-out of gas-powered vehicles, with the sale of these types of cars banned starting in 2035. At least 15 other states have backed California's zero-emission standards, with several moving towards adopting them.

Automotive OEMs will have to comply with these net-zero emissions targets. However, the experts at AlixPartners predict that manufacturers will have to rely on their suppliers to drive 25% to 50% of the improvements needed to reduce emissions. They say the majority of total automotive-related emissions come from indirect sources that include both upstream purchased goods and services as well as downstream logistics. These are called Scope 3 emissions, which differ from Scope 1 emissions, which are generated directly by the company, and Scope 2 emissions which are indirect purchased emissions such as electricity, heating and cooling.

In its 2022 Global Automotive Outlook, AlixPartners estimates it will cost $70 billion to transition the supply base to battery electric vehicles (BEVs) through to the end of the decade. It predicts that these costs could be reduced by up to 60% if the supply base's conversion from internal combustion engine (ICE) to BEV is managed proactively.

While OEMs always want good relationships with suppliers, it will be important for OEMs to view them as partners in the transition to EVs. Supply chain disruptions brought on by the pandemic may have strained some relationships or created new opportunities. This new era for the industry could have an even bigger impact on supply chain dynamics. OEMs should work with their suppliers and evaluate what steps could be taken to help move towards net-zero targets.

> *Bad actors could hack the app to fetch a user's profile with the VIN and obtain the vehicle owner's name, phone number, address and car details. Hackers could also potentially remotely control the vehicle, lock or unlock it, start the car and perform other functions."*

Cybersecurity threats in the automotive industry

Most drivers like the added convenience and safety offered by "smart features" such as automatic crash detection, navigation, and remote locking and unlocking. Telematics systems are the technology that enable these functions by obtaining data about a car's GPS location, speed, turn-by-turn navigation and maintenance requirements.

Cars also have more and more advanced "infotainment" systems that don't perform critical driving or safety functions, but might track call logs, voice commands, text messages and more. One of the U.S.'s leading audio entertainment companies reports that it offers more than 50 connected vehicle services to more than 12 million active vehicles on the road.

Security researchers discovered a coding flaw in the provider's service that allowed the researchers to remotely unlock, start, locate, flash and honk the horn in cars from four major OEMs. After reaching out to one of the automakers and the entertainment provider, the researchers were told the issue had been resolved.

The security experts did note that while they could hack into some of the cars' features, they could not control any driving functions. The companies also reported that there were no mishaps or any indications of malicious use from the potential security breach.

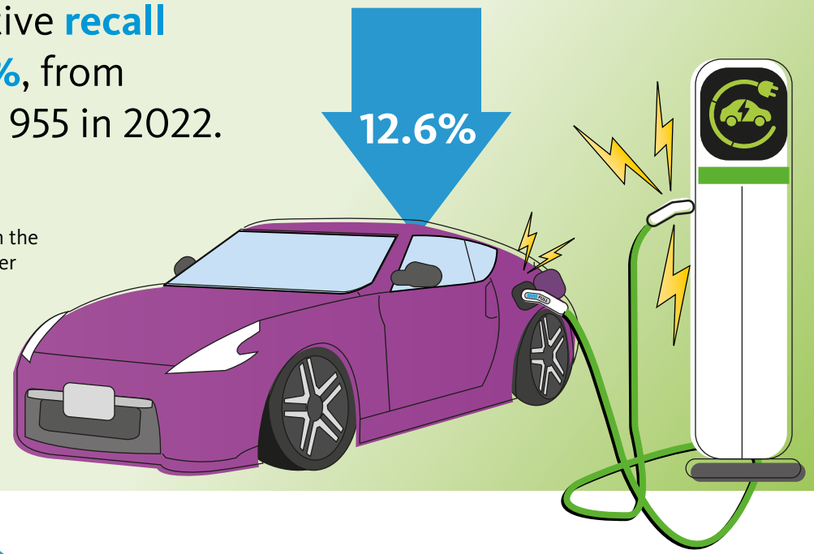
While this flaw seems to have been fixed before damage was done, the threat still exists. According to the research team, the entertainment company built its infrastructure around the sending and receiving of this telematics data. Customers could authenticate the data and execute commands or obtain information about their cars using a mobile app tied to the OEM.

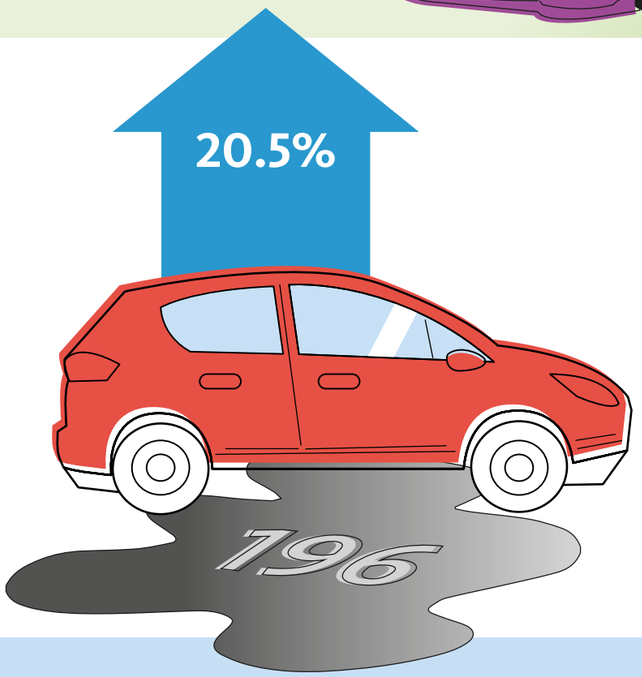
These types of OEM apps are typically linked to a car's vehicle identification number (VIN) which is used to relay information and commands between the app and its servers. That means bad actors could hack the app to fetch a user's profile with the VIN and obtain the vehicle owner's name, phone number, address and car details. With the VIN, hackers could also potentially remotely control the vehicle, lock or unlock it, start the car and perform other functions.

Experts suggest developing industry standards and standardizing protocols around these types of applications to reduce these risks. Automakers also need to confirm that their third-party suppliers have a robust cybersecurity plan in place to constantly check for flaws and vulnerabilities. Several manufacturers have come under fire in the past for not protecting customers' private information, even if they were not aware they were exposing it.

Annual automotive **recall events fell 12.6%**, from 1,093 in 2021, to 955 in 2022.

Despite this drop, only 3 years in the last 10 have experienced a greater number of events.



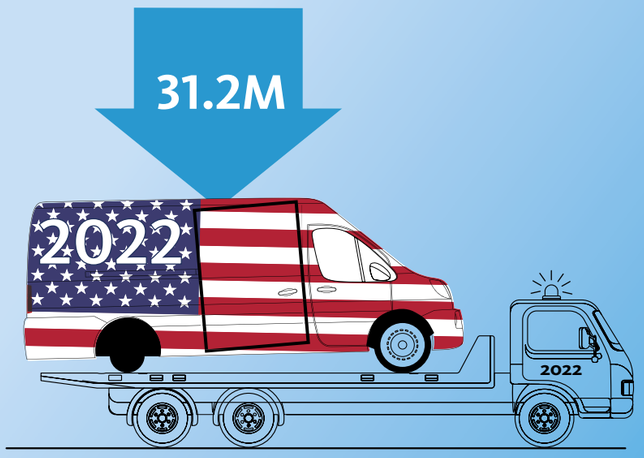


Equipment was the **leading cause of recall events** in 2022, accounting for 196 (or 20.5%).

While dominating events, the number of impacted units accounted for only 1.9% of the annual total.

The number of **vehicles recalled in the U.S.** in 2022 fell to a 9-year low (31.2M).

This comes despite a 43.6% uplift in vehicles recalled in Q4 (from 5.2M to 7.5M).



JANUARY

2023 insight

There were 42 U.S. automotive recalls in January 2023, a 46.8% reduction compared to the monthly average of 79 events in Q4 2022. The 682,891 units recalled in January were also significantly fewer than the Q4 monthly average of 2.51 million units in 2022.

382,759 (or 56.0%) of the units recalled were related to a single event involving back over prevention concerns from a possible malfunction with the vehicles' rearview camera. There were two other recalls prompted by back over prevention issues, though involving significantly fewer units, making this the highest category for recall causes by total units in January 2023. Electrical systems recalls were the second highest category by unit, linked to 93,205 units.

By events, faulty equipment was the leading cause of NHTSA recalls in January 2023, with 12 events. This is consistent with Q4 2022 trends. Electrical systems were the second most common reason and were linked to eight recalls in the first month of 2023.

2022 BY THE NUMBERS

The National Highway Traffic Safety Administration (NHTSA) recorded a 12.6% decrease in automotive recalls for 2022 compared to 2021. The total number for 2022 was 955, compared to 1,093 in 2021. Between Q3 and Q4 2022, there was also a decrease in recall events though the difference was smaller. The 237 recalls in Q4 2022 was 6.0% fewer than the 252 recalls in Q3.

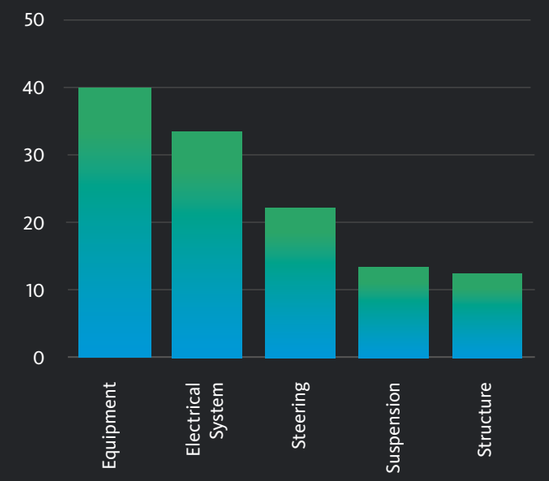
While the number of recalls in Q4 was slightly down compared to the previous quarter, the number of units affected was up 43.6% with 7.52 million units in Q4 compared to 5.23 million in Q3. Year-over-year, the industry finished with 3.58 million fewer units recalled in 2022 compared to 2021, and the fewest units recalled annually in the last nine years.

For the eighth consecutive quarter, equipment was the category most impacted by recall events. Such has been its dominance that there have only been three quarters in the last five years where equipment has not been the causing cause. However, the 40 equipment recalls recorded in Q4 reflected a 23.1% drop compared to Q3. Electrical systems had the second-highest number of recall events at 33, but that was a drop from 41 recalls in Q3.

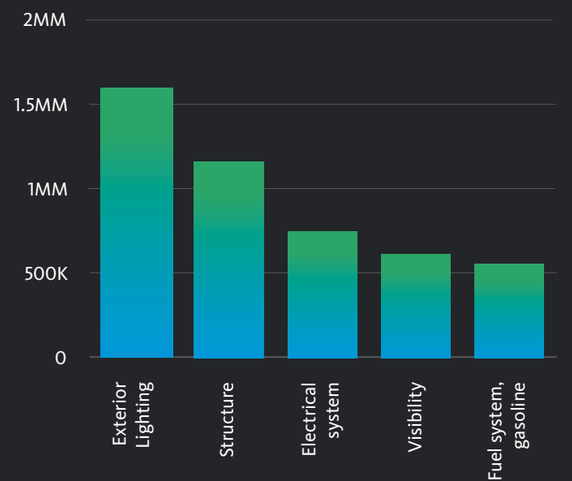
In terms of units impacted, exterior lighting led the categories. Although it was only cited in eight recalls, the category was responsible for 1.60 million units recalled in Q4, or 21.3% of all units. Unlike last year, air bags only totaled 145,172 units in Q4 2022, compared to 571,971 in Q4 2021.

Automobiles continue to be the largest category of NHTSA recalls, with events in Q4 slightly decreasing to 215, compared to 227 last quarter. The number of equipment recalls quarter-to-quarter also was lower, going from 23 to 16. We saw the opposite with tire recalls, which increased to five recalls compared to two in Q3, and child seat recalls which increased to one after seeing no events in Q3.

NUMBER OF RECALL EVENTS BY CATEGORY IN Q4



NUMBER OF UNITS RECALLED BY CATEGORY N Q4



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TOP REGULATORY ISSUES AFFECTING THE AUTOMOTIVE INDUSTRY IN 2023

The automotive industry is facing a time of change and challenge. Supply chain issues continue to be a problem, while manufacturers also face rising costs and increased regulations. Meanwhile, the focus has shifted from traditional vehicles toward electric vehicles (EVs) with lawmakers introducing rules to promote the sale of EVs and speed consumers' adoption of them.

Recent developments in motor vehicle safety regulations

On November 15, 2021, the Biden Administration signed the Infrastructure Act into law. Many of its provisions impose rulemaking mandates upon the National Highway Traffic Safety Administration (NHTSA). While we are still waiting for most of the final rules from the Department of Transportation (DOT), there are several specific directives in the Act that automakers should be watching.

These new regulatory actions will require manufacturers to install specific equipment in their vehicles including automatic shutoff devices on keyless internal combustion vehicles aimed at preventing carbon monoxide poisoning, though this does not apply to vehicles with traditional keys or electric vehicles, (Section 24205 of the Act). Other actions include, forward collision warning systems, automatic emergency braking systems, lane departure warning and lane keeping assist systems, (Section 24208); advanced impaired driving technology, (Section 24220); rear-seat alert technology, (Section 24204); new performance standards for crash avoidance technology, (Section 24208); and adaptive driving beam headlamps, (Section 24213).

The law further requires that the DOT conducts studies on the causes of commercial vehicle crashes, rollaways, reducing driver distraction, and detecting pedestrians and bicyclists by connected vehicle system. The findings of these studies could lead to additional federal rules or performance standards.

The mandate requiring future vehicles to passively monitor drivers for signs of drunk driving has generated significant interest. There are still many questions about how this would be implemented. Automakers are examining several options and various types of technology are currently under consideration by NHTSA. Some possibilities are using infrared cameras that monitor the driver's movements and reactions, checking to see if the driver is paying attention to the road and searching for signs of impairment; built-in Breathalyzers that could sample cabin air; sensors that use infrared lights to detect the presence of alcohol in the blood flowing beneath the driver's skin through their fingertips; windshield- or dashboard-based sensors that monitor the driver's breathing patterns; and cameras that peer into the driver's eyes to make sure the person is constantly paying attention to the road.

Since the passing of the bill, NHTSA has only issued one rule, which was the requirement for adaptive driving beam headlamps in February 2022. Senators Edward Markey (D-MA), Richard Blumenthal (D-CT), and others are putting pressure on the NHTSA Administrator Ann Carlson to implement rules mandated by the bill and prior legislation.

While it is not clear ultimately what standards the DOT will require on these specific directives, manufacturers should monitor NHTSA's federal rules and start preparing. The fact that these safety standards will require vehicles to be more technologically-advanced presents additional concerns for manufacturers, such as how to protect consumers' privacy and safety.

Proposed "Frontover" Legislation

Senator Blumenthal has also proposed legislation that would require all new vehicles to come equipped with cameras, sensors, or other technology to improve drivers' visibility and perception of objects that may be in front of their vehicle. The Standards to Prevent (STOP) Frontover Act directs NHTSA to begin the rulemaking process for the standard within one year and issue a final Federal Motor Vehicle Safety Standard (FMVSS) within two years.

It also requires NHTSA to formally define the term "frontover" to standardize its definition and allow for more accurate data collection. This proposed legislation is something that auto manufacturers should be following as well, especially since one focus is to protect children and child-safety legislation often gains the attention of both regulators and the media.

Privacy and Cybersecurity Concerns

Privacy and cybersecurity should be at the forefront of the auto industry's concerns, since the industry will need to use more technology in vehicles with the new wave of EVs, vehicles with autonomous driving technology, and proposed regulations mandated in the Infrastructure Act. While there is no federal law in place that specifically governs privacy for automakers, the Federal Trade Commission (FTC), which is the federal agency that oversees privacy issues, recently sought to implement further rules on privacy and data security.

Some states, such as California, Colorado, Connecticut, Virginia, and Utah are implementing privacy laws that would impose significant new obligations on automakers that collect and process personal data. Some of these laws include the requirement for "opt-outs" for the sale or sharing of personal or sensitive data. Others require entities that act as "data controllers" obtain "opt-in" consent from consumers before processing precise geolocation data. These new regulations raise important questions for

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manufacturers about when data is being collected and processed, where data remains on the vehicle when it is sent to the cloud, and how such obligations involve operations by manufacturers vs. vehicle owners.

A vehicle's infotainment system can collect and store significant amounts of information on its users such as phone contacts, call logs, photos, messages, and social media on the system. The rise of autonomous vehicles will only increase the data automakers can collect, making the need to monitor and keep up-to-date with data protection legislation imperative.

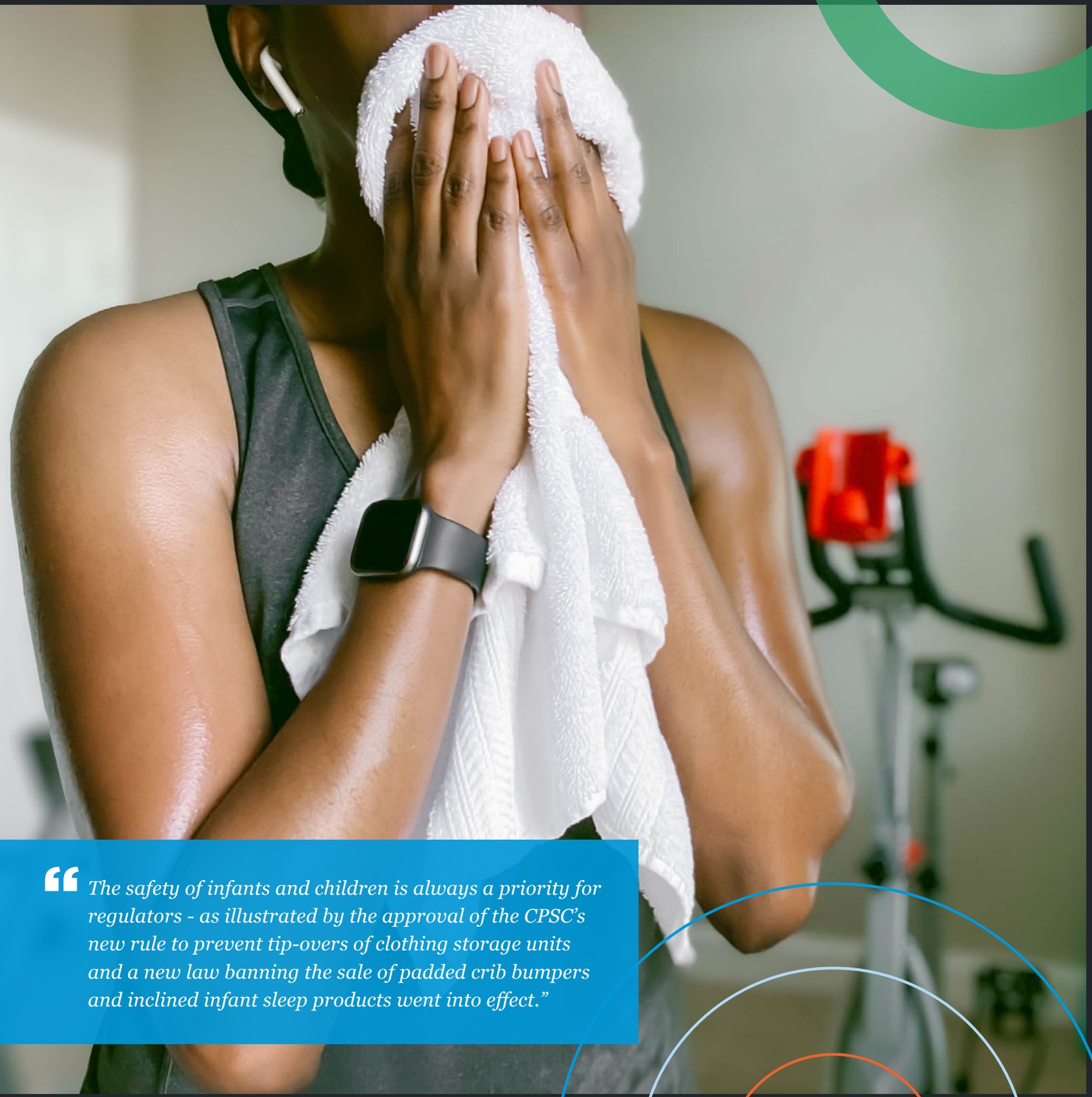
These same infotainment systems are entry points in vehicles that present serious cybersecurity risks for auto manufacturers, as are in-vehicle Wi-Fi and Bluetooth capabilities. Cybersecurity standards for vehicles have only just started to be considered. The United Nations Economic Commission for Europe (UNECE) recently issued UN R155 that came into effect on July 1, 2022, for new vehicles. These rules govern cybersecurity and cybersecurity management systems for all vehicles sold in major markets outside of the U.S., Canada, and China.

Managing vehicle cybersecurity risks in the car itself and across interconnected systems and components needs to be a priority for automotive original equipment manufacturers (OEMs) and component manufacturers. The question becomes how to protect vehicles from cybersecurity threats. To ensure proper security, manufacturers and suppliers must establish protocols for responding to incidents; collaborate and communicate with other providers to share security best practices and send alerts of potential vulnerabilities; manage and assess risks and resolve those that can lead to safety and data security issues. Furthermore, they should consider security as part of the design process for the entire vehicle system, including the car, the network communications, the cloud services, and the connected apps on drivers' phones.

Manufacturers must mitigate risks along the supply chain by securing vehicles in the design stage, detecting and responding to security incidents across a vehicle fleet, and providing safe, secure software updates that do not compromise vehicle security. It is crucial for manufacturers to be proactive in protecting data and addressing the risk of cyber threats with the growth of EVs and the new technology being implemented in vehicles.

Next steps

With the challenges ahead for the automotive industry, there are also opportunities. The companies that are innovative and proactive have a chance to attract new customers and set the pace for the industry. However, it will require a lot of communication with partners up and down the supply chain and the ability to look at problems in new ways, since the sector is evolving so quickly.



> *"The safety of infants and children is always a priority for regulators - as illustrated by the approval of the CPSC's new rule to prevent tip-overs of clothing storage units and a new law banning the sale of padded crib bumpers and inclined infant sleep products went into effect."*

CONSUMER PRODUCTS

As noted by Partners at Dentons US LLP in our 2022 Edition 3 Recall Index, the Consumer Product Safety Commission's (CPSC's) enforcement behavior became increasingly aggressive in 2022. The industry saw more robust civil penalties and attention-grabbing unilateral press releases. A total of $38.0 million in fines was issued by the Commission in 2022, after no fines at all in 2019 and 2020, and only $7.95 million in 2021.

This trend seems likely to continue in 2023. The Commission kicked off the new year by announcing that a major exercise equipment brand had agreed to pay a $19,065,000 civil penalty – one of the largest civil penalties in CPSC's history.

The company had been charged with breaking the law and knowingly failing to immediately report a defect in one of its products to the CPSC. The Commission determined that flaw could cause a substantial product hazard and thereby created an unreasonable risk of serious injury to consumers. The CPSC also alleged that the company knowingly distributed recalled treadmills in violation of the Consumer Product Safety Act (CPSA).

In addition to the fine, the company must maintain an enhanced compliance program and system of internal controls and procedures to ensure compliance with the CPSA. It is also required to file annual reports regarding its compliance program and system of internal controls for the next five years.

> *Lawyers with Winston & Strawn predict a rise in class action litigation, especially if companies make advertising claims about their products being "natural," "environmentally friendly," or "healthy," but contain what is being categorized as a dangerous chemical."*

Other items on regulators' agenda in the fourth quarter of 2022 were how to address perfluoroalkyl and polyfluoroalkyl substances (PFAS). More and more authorities are adding new requirements around the use of these "forever chemicals." Food packaging seems to be the latest focus for many states, while the Environmental Protection Agency (EPA) is seeking public comments on strengthening federal oversight.

Consumers seem to be weighing the environmental impact of a product more heavily when they make purchasing decisions. In response, the Federal Trade Commission (FTC) is trying to make sure the information they have is accurate and truthful. The Commission is looking for public comment on its "Green Guides," including examining perceptions around a variety of terms such as "recyclable" and "organic."

The safety of infants and children is always a priority for regulators. That was illustrated again in the fourth quarter as the CPSC's new rule to prevent tip-overs of clothing storage units was approved and a new law banning the sale of padded crib bumpers and inclined infant sleep products went into effect.

PFAS continue to create risks, regulatory burdens and confusion

Perfluoroalkyl and polyfluoroalkyl substances, or PFAS, continue to be under the regulatory spotlight. This class of more than 3,000 synthetic chemicals is found in a wide range of consumer, commercial and industrial products including food packaging, high-performance outdoor clothing, household cleaners and carpeting.

There is little consistency among state and federal regulators around how PFAS are monitored and controlled. This ever-changing patchwork of rules makes it increasingly difficult for manufacturers to keep up with compliance. In December 2022, the Environmental Protection Agency (EPA) proposed a rule that would increase reporting for PFAS substances in the Toxics Release Inventory (TRI), part of the Emergency Planning and Community Right-to-Know Act (EPCRA).

Under the EPCRA, companies are required to report if they manufacture, process or otherwise use 100 pounds or more of any PFAS compound listed on the TRI. Now the EPA has proposed PFAS compounds on the TRI should be classified as "Chemicals of Special Concern." This new designation would impact manufacturers in three ways. First, any amount of PFAS would need to be reported. Currently, concentrations of less than 1% of listed PFAS chemicals, considered "*de minimis concentrations*," are given an exception.

A second consequence would be that the de minimis exception for supplier notifications would also be eliminated. Currently, if a product contains less than a 1% concentration of a PFAS substance, it is not necessary to notify downstream customers even though PFAS are now subject to TRI reporting.

The third change would be that companies would need to use a specific reporting form for the listed PFAS substances. This may seem like a minor adjustment, but it would mean compliance checks and processes would need to be updated to ensure the proper documentation is going to the EPA.

While it might be helpful to have more consistent federal regulations for PFAS instead of a vastly different set of state-by-state requirements, if approved the changes to EPA reporting will be more burdensome.

In addition, states continue to implement their own restrictions on the use of PFAS chemicals. According to legal experts at Sheppard Mullin, nine states have enacted regulations to ban PFAS in food packaging. New York's laws went into effect in December 2022 and California's were enacted on January 1, 2023. Maine had passed reporting requirements that were scheduled to take effect on January 1, 2023, but the Maine Department of Environmental Protection (DEP) updated its website clarifying that product packaging, including food packaging, is exempt from the reporting requirements. However, at least 10 more states have pending proposals regarding PFAS and food packaging.

With more regulations around PFAS and a lack of clear national standards, lawyers with Winston & Strawn predict a rise in class action litigation, especially if companies make advertising claims about their products being "natural," "environmentally friendly," or "healthy," but contain what is being categorized as a dangerous chemical. These lawsuits could be brought as violations of states' consumer protection acts, breaches of express and implied warranties, fraudulent and negligent misrepresentation or negligent failure to warn, among other causes.

Companies have the added burden of not only complying with varied and rapidly-evolving PFAS regulations, but also the need to ensure that there are no missteps with advertising and marketing claims.

> *Consumers are making more purchase decisions based on the environmental impact of a product or company, so the Commission wants to ensure those claims are truthful."*

FTC proposes updates to Green Guides

In December 2022, the Federal Trade Commission (FTC) opened a public comment period on proposed changes to the "Green Guides for the Use of Environmental Claims" (the Green Guides). The Green Guides are designed to help advertisers avoid making environmental marketing claims that are unfair or deceptive under Section 5 of the FTC Act and were last updated in 2012.

According to Samuel Levine, Director of the Bureau of Consumer Protection, consumers are making more purchase decisions based on the environmental impact of a product or company, so the Commission wants to ensure those claims are truthful.

The FTC is soliciting feedback on questions around the continuing need for the guides and their effect on the accuracy of various environmental claims among other topics. It is also looking for comments around specific issues such as carbon offsets and climate change, as well as claims associated with several terms including "recyclable," "compostable," "degradable," "ozone-friendly," "organic," and "sustainable" among others.

In a statement, FTC Chair Lina M. Khan noted that while many products make claims about their low carbon footprint or energy efficiency, it is impossible for the average consumer to verify the companies' statements. She also stated that to be effective, the Green Guides must keep up with developments in both science and consumer perception.

As experts with Seyfarth note, while the guidance in the Green Guides is non-binding, the FTC and the National Advertising Division of the Better Business Bureau have considered the guidelines when deciding whether or not enforcement actions are appropriate. In addition, plaintiffs' attorneys will cite the guides in putative consumer class action complaints.

The public comment period closed on February 21, 2023. Once the updated Green Guide is finalized, it will be interesting to see if the FTC is more aggressive about enforcement. It has averaged less than three environmental marketing cases per year since 2016, with only two in all of 2022.

More child safety regulations take effect

In October 2022, the Consumer Product Safety Commission (CPSC) approved a new federal mandatory safety standard for clothing storage units (CSUs) to prevent tip-overs. The standard mandates stability requirements that reflect "real-world factors," such as multiple open drawers and tests to replicate the force a child exerts while climbing or pulling on a CSU.

From January 2000 through July 2022, there have been 43 recalls in response to tip-over hazards of CSUs, involving more than 21 million units. According to the Commission, young children face the biggest risk of injury or death from tip-over incidents with CSUs. It reported 234 fatalities from January 2000 through April 2022 that resulted from clothing storage unit tip-overs and estimated that there were an average of 5,300 related injuries annually from 2006 through 2021 that were treated in U.S. hospital emergency departments.

The new standard also includes test methods for CSUs with interlocks, which prevent all the drawers from being opened at once. Under the new rule, all CSUs must be marked and labeled with safety and identification information and display a hang tag providing performance and technical data about the product's stability. The new rule will take effect 180 days after it is published in the Federal Register.

In other child safety news, the Safe Sleep for Babies Act of 2021 went into effect on November 12, 2022 after being signed into law in May 2022. This federal law makes it is unlawful to sell, offer for sale, manufacture for sale, distribute in commerce or import into the United States padded crib bumpers and inclined infant sleep products with an incline of 10 degrees or more.

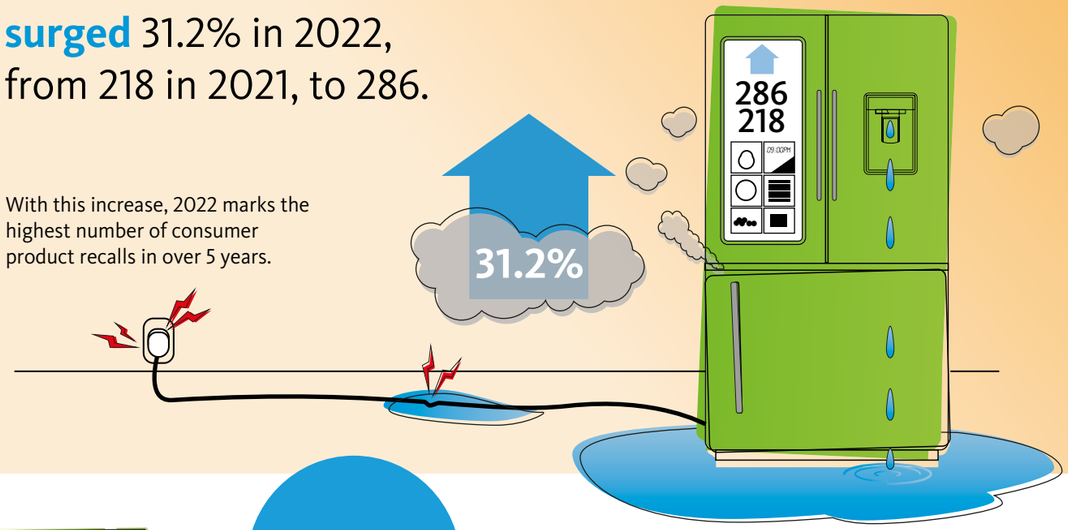
Manufacturers, distributors and retailers need to be mindful that in addition to the Safe Sleep for Babies Act, these types of products are also regulated by the CPSC under its Safety Standard for Infant Sleep Products, which went into effect in June 2022. The CPSC standard is much broader than the federal law and made it unlawful to sell non-compliant infant sleep products including inclined sleepers, travel and compact bassinets, in-bed sleepers and any flat sleeping products that do not comply with the mandatory Safety Standard for Bassinets and Cradles.

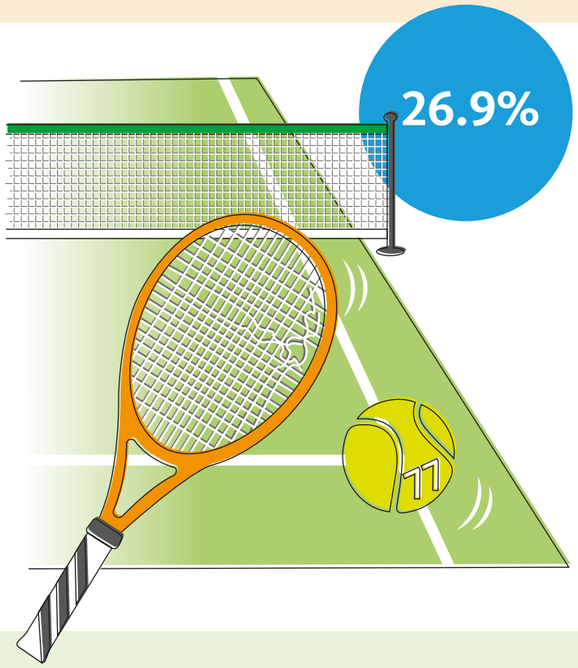
Attorneys with Morgan, Lewis and Bockius caution companies that simply having packaging or marketing materials depicting a sleeping child, animal or cartoon figure could be interpreted as a sleep product by the CPSC and regulated by the standard.

Manufacturers, distributors and retailers should expect close monitoring from regulators to make sure they are complying with the new rules. Protecting infants and children has proven to be a top priority for regulators.

CPSC **recall events surged** 31.2% in 2022, from 218 in 2021, to 286.

With this increase, 2022 marks the highest number of consumer product recalls in over 5 years.





Sports & Recreation was the **leading category of recall** in 2022 (with 77 events or 26.9%).

Sports & Recreation has now been the leading category for 7 of the last 10 years, beaten only by Home Furnishings & Décor in 2020, 2014, and 2012.

Despite events increasing, **total impacted units almost halved** from 42.8M in 2021, to 23.4M.

Personal care products dominated in 2022 with 5.3M units, followed by Electronics with 3.5M.

2022 BY THE NUMBERS

The CPSC announced 78 recalls in Q4 2022, which is an 18.2% increase from the 66 events recorded in Q3 2022. In terms of year-over-year numbers, 2022 hit a six-year high with a total of 286 events. That is up 31.2% compared to 2021.

However, in terms of units recalled, there was a 21.4% drop from 5.43 million units in Q3 to 4.26 million units in Q4 2022. Year-over-year, the change was even more dramatic. There were 42.83 million total units recalled in 2021 in the consumer products sector, and only 23.37 million units for all of 2022. However, it is worth noting that 2021 was a particularly active year in terms of units recalled. The figures for 2022 are in line with annual numbers from 2018-2020 in terms of both total units and average recall size.

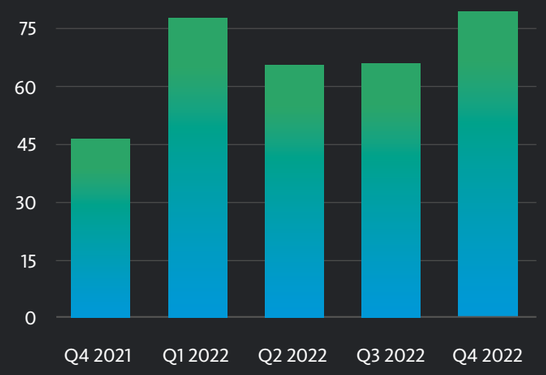
The number of reported incidents of consumer product recalls increased by 29.3% to 2,995 in Q4 compared to the previous quarter. Injuries also increased, rising from 182 in Q3 to 274 in Q4, although the number of deaths linked to recalled consumer products stayed at three.

Accounting for 21 events in Q4, Sports & Recreation has now remained the leading category of recall for eight consecutive quarters. That category also had the most incidents (1,993), injuries (162) and one reported death. Electronics came in second with 13 recalls, including 454 incidents and 83 injuries. Toys came in third with nine recalls that included 35 incidents.

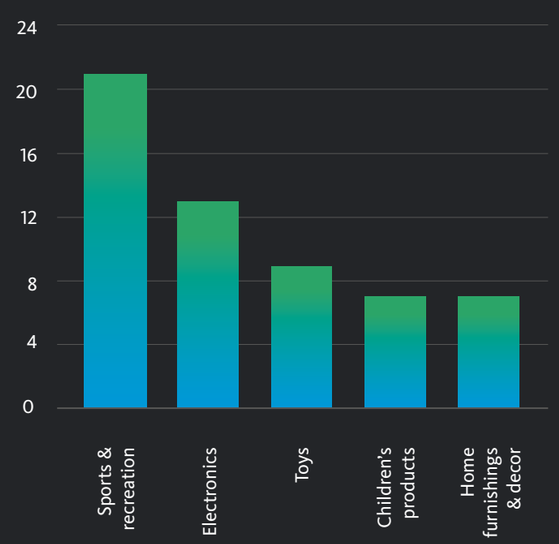
In terms of recalled units, electronics was the leading category with 1.63 million, or 38.1% of the total units in Q4. Sports & Recreation had the second-most for the quarter at 805,590 units recalled. In third was Home Appliances with 691,500 units, which included one individual recall impacting 663,500 units of washing machines, the highest single recall by units impacted in Q4.

After issuing no fines in all of 2019 and 2020 and only $7.95 million in fines in 2021, the CPSC issued two fines totaling more than $38.0 million in 2022.

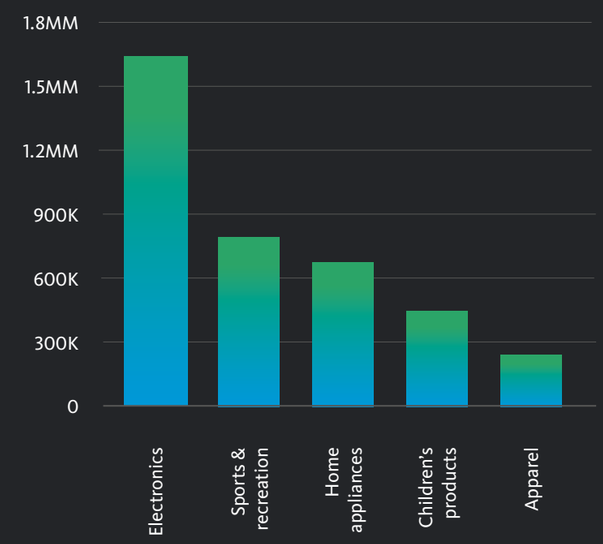
NUMBER OF RECALLS BY QUARTER



NUMBER OF RECALL EVENTS BY PRODUCT CATEGORY IN Q4



NUMBER OF UNITS RECALLED BY PRODUCT CATEGORY IN Q4



JANUARY

2023 insight

There were 24 consumer product recalls in January 2023, which is similar to the Q4 2022 monthly average of 26. However, the number of units recalled increased from Q4 2022's monthly average of 1.42 million units to 5.86 million units in January 2023, a jump of 312.0%.

As a category, Children's Products had the most recalls, with 12 events reported by the CPSC. Sports & Recreation had five recalls and Home & Furnishing had two. Children's Products was also the leading category by units in January 2023. A single recall of rocking sleepers accounted for 4.70 million units, driving the total for the category to 5.45 million units in January 2023. In terms of risk, there were nine recalls linked to burns, five to fires and four to injuries. That made these concerns the first, second, and third most common reasons for consumer product recalls.

IBRAHIM JILANI, GLOBAL DIRECTOR,
CONSUMER TECHNOLOGY, **UL SOLUTIONS**

IS ENOUGH BEING DONE TO KEEP THE PUBLIC SAFE FROM LITHIUM BATTERY-OPERATED PRODUCTS?

Many products we use every day are powered by lithium batteries including wireless earbuds, electric personal care and grooming devices, cellphones, tablets, power tools, power banks, hoverboards, e-scooters, e-bikes, and electric vehicles (EVs). The United Nations (UN) considers lithium battery-operated products dangerous goods under UN Class 9 for miscellaneous substances and articles. While this classification is primarily for transporting these products, the risk of explosion and fire can also occur during everyday use.

Yet, there are no U.S. consumer safety laws that require manufacturers of these types of products to work with an accredited independent third-party or meet any type of national consensus standards. The lack of required safety standards in the U.S., especially when a benchmark for these standards exists, poses a threat to public safety and can have real human, consumer trust, and financial impacts.

The danger is from an event known as "thermal runaway," which happens when the energy from a lithium cell is released as thermal energy, but the cell is not able to dissipate the energy. This can result in an explosion, fire, and venting of toxic gases. Any lithium battery-operated product has a risk of experiencing thermal runaway.

In 2022, more than 200 fires and six deaths were attributed to lithium batteries and/or lithium battery-operated products in New York City alone. Hundreds of other fires were reported throughout the U.S., Canada, and other countries. On December 20, 2022, the U.S. Consumer Product Safety Commission (CPSC) released a statement about micromobility devices, a specific type of lithium battery-operated product. The CPSC guidance stated their expectation that micromobility devices for consumer use, which include e-bikes, e-scooters, hoverboards, and personal e-mobility devices, be designed, manufactured, and certified by an accredited testing laboratory to meet product safety standards. The CPSC has firmly set the criteria for this type of product. While it's a start, more can and should be done to further improve public safety.

It's important to note that federal regulation 29 CFR 1910 Subpart S provides the mandatory requirement for electrical product safety from Occupational Safety and Health Administration (OSHA) for product manufacturers or U.S. employers. For workplace safety, OSHA published a bulletin in 2019 that they expect all lithium battery-operated products to be third-party certified, citing the aforementioned regulation.

The requirements from CPSC and OSHA for independent and impartial third-party product safety certification reduce the risk of explosion, fire, and electric shock. This, in turn, minimizes injuries, death, and property damage. U.S. regulators have a goal for consumers and workers: enhance the safety of the electrical products they interface with and use daily. Studies show that there is significantly less risk with third-party certified products compared to self-declared or non-certified products.

A recent study showed 90% of mobile phone battery packs that were not manufactured by the device's original equipment manufacturer (OEM) do not comply with UL 2054, the standard for safety of household and commercial batteries. This statistic is alarming and puts the public in danger when using non-OEM battery pack replacement sources. It also highlights the cross-section of the recently proposed or passed right-to-repair law(s) that does not require independent, third-party product safety certification for non-OEM replacement components and their use in OEM end products.

Consumers should not put their safety at risk when taking advantage of new right-to-repair laws. There is a critical need to leverage third-party product safety certification of lithium batteries and the end products they are used in to help safeguard the public from explosion, fire, and electric shock safety hazards in any product from any OEM.

One common misconception relates to the terms "tested to," "compliant with," "certified to," and "UL certified," around product safety and standards. Moreover, there is distinction among testing, complying, and certifying to a specific standard.

- The term **"tested to"** a specific standard typically means a manufacturer or another entity in the supply chain has tested the product themselves or through a third-party laboratory that might be accredited to ISO/IEC 17025 for testing. It is a self-declaration, not a third-party claim. In this case, it is almost certain the product has not complied with all of the requirements of the standard that are applicable since construction, design, material, and user manual requirements have not been evaluated. Simply stating that testing was done to a specific standard does not mean the product has met all the requirements of that standard.

- **"Compliant with"** a standard is another term that often means a product was self-evaluated and the manufacturer has determined that it complies with the full standard. It means no accredited third-party certification organization has reviewed the conformity of the lithium battery-operated product. Claims like this cannot be treated as impartial or reliable. Those must come from trusted organizations such as accredited ISO 17065 Certification Organizations or OSHA Nationally Recognized companies.

- If a company claims its product is **"certified to"** a certain standard, it usually means that the product has obtained third-party certification from a certification organization. The certification organization's mark will also be on the product and/or packaging. For example, consumers can be sure they are buying a **"UL Certified"** product by looking up the item on UL Product iQ® and searching by manufacturer name and product model number. This publicly-accessible database of product safety certification records allows stakeholders and consumers to confirm that the product has met national safety standards by an independent and impartial organization that is trusted for public safety. This is the only place UL Certified products can be searched. If certified by another certification organization, then their database would be where to search.

It is critical to public safety that regulators, retailers, employers, and other safety stakeholders seek more transparency and have a higher degree of trust in the products used every day. Independent and impartial third-party certification of electrical products do just that — increase consumer trust and reduce risk. Lawmakers and policymakers must consider how the U.S. has increased electrical product safety over the past 100 years and continue to implement mandatory laws to protect consumers.

The bulletins from CPSC and OSHA show these agencies understand the value and credibility of national consensus standards and the risks that lithium batteries and their end products present. Regulators need to apply the same best practices in place for electrical products to lithium battery-operated products to help make U.S. consumers safer.

FOOD AND DRINK

After being confirmed by the Senate in December 2022, Dr. Jose Emilio Esteban was sworn in as the U.S. Department of Agriculture's (USDA's) Under Secretary for Food Safety on January 4, 2023. The Under Secretary role is the nation's highest food safety position and provides oversight of the USDA's Food Safety and Inspection Service's (FSIS's) policies and programs. The office had been vacant since January 2021, though Dr. Esteban had been nominated in November 2021. It is too early to tell if his approach to safety and enforcement will differ from his predecessors. He has worked at FSIS since 2001, most recently as Chief Scientist, so he knows the programs well.

In December, the FDA released the findings from its months-long independent evaluation of the Human Foods Program. The expert panel had numerous suggestions on how to improve the program's culture, structure and leadership, resources and authorities. There were strong recommendations to overhaul the program's structure. There were also suggestions to use its current authority to conduct more mandatory food recalls.

The agency also issued the Food Traceability Final Rule, a critical part of the FDA's New Era of Smarter Food Safety Blueprint that implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA). The rule requires companies that manufacture, process, pack or hold specific foods to maintain specific data about their products as they move along the supply chain and provide that product information to partners. The goal is to improve the availability of information needed for effective and efficient tracing of foods and food products.

Sesame officially became the ninth major food allergen that companies must declare on food packaging when the Food Allergy Safety, Treatment, Education and Research (FASTER) Act took effect on January 1, 2023. To help companies meet the requirements of the new law and to provide clarification around other changes to food labeling and allergen requirements, the FDA published a draft guidance: "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5); Guidance for Industry."

> *"The "Operational Evaluation of FDA's Human Foods Program," report urges the FDA to make bolder, more frequent use of its existing powers including using its mandatory recall authority and collecting user fees in mandatory recall situations."*

Report on Evaluation of FDA Human Foods Program

In July 2022, The U.S. Food and Drug Administration (FDA) Commissioner Robert Califf announced that the agency had charged the independent Reagan-Udall Foundation with evaluating the FDA's Human Foods Program (HFP), which includes the Office of Food Policy and Response (OFPR), Center for Food Safety and Applied Nutrition (CFSAN), as well as relevant parts of the Office of Regulatory Affairs (ORA).

The much-anticipated 50-page report, the "Operational Evaluation of FDA's Human Foods Program," was released on December 6, 2022 and offered findings and recommendations in four areas of the Human Foods Program: culture, structure and leadership, resources, and authorities.

Structure and leadership was the key area that the report focused on, pointing out the lack of a "clear leader or decision-maker, outside of the Commissioner" and making strong recommendations to make structural changes and establish clear lines of authority, among other improvements.

According to the expert panel, the issues with structure also contributed to challenges for the culture of the HFP and impacted the program's effectiveness. Some of the recommendations included establishing a clear leader who could develop and promote a vision and mission for the HFP, as well as committing to more transparent and predictable decision-making.

Given the scope of the programs under the HFP and overall staffing at the FDA, it should not be surprising that the report found the organization was significantly under-resourced. Its recommendations to help address this included formulating an appropriations strategy to increase funding as well as looking to expand the use of states' capabilities. The report also suggested the FDA more fully implement the industry fee authorities provided by the Food Safety Modernization Act (FSMA), which is said would help fund some of the changes that needed to be made.

This fourth area around the HFP's authorities could have significant implications for the food companies and distributors. The report urges the FDA to make bolder, more frequent use of its existing powers including using its mandatory recall authority and collecting user fees in mandatory recall situations. It also suggests the agency apply more of its existing authority around other areas such as data sharing, nutrition labeling and instituting a routine assessment for determining if food substances should be generally recognized as safe (GRAS).

Commissioner Califf issued a statement after the release of the report that promised a public update from the FDA on its new vision for the HFP at the end of January 2023 and additional public updates by the end of February 2023, which would include the planned leadership structure and any changes to key internal processes and procedures.

Food Traceability Final Rule requires more data from stakeholders

On November 15, 2022, the FDA published the Final Rule: Requirements for Additional Traceability Records for Certain Foods (Food Traceability Rule). It is designed to allow potentially contaminated food to be identified and removed from the market more quickly. Ultimately, the agency wants to lower the number of foodborne illnesses and/or deaths.

The rule applies to companies that manufacture, process, pack or hold certain foods. Those foods are identified on the Food Traceability List (FTL) and include all fresh-cut fruits and vegetables, shell eggs and nut butters, as well as certain fresh produce including leafy greens, cucumbers, melons, sprouts, and tomatoes, as well as ready-to-eat deli salads, some cheeses and certain fresh, frozen and smoked seafood products.

Under the final rule, companies that manufacture, process, pack or hold foods on the Food Traceability List (FTL) must maintain and provide to their supply chain partners key data elements (KDEs) for certain critical tracking events (CTEs) in the food's supply chain. According to the FDA, this framework will provide the information needed for effective and efficient tracing of foods and food products.

The rule lists six CTEs including harvesting, shipping and receiving for which specific KDEs must be created and maintained. The information that firms must keep and send to supply chain partners depends on the type of activity they perform. As part of the data sharing, supply chain partners must assign, record and share traceability lot codes (TLCs) for FTL foods and link the TLCs to other identifying information for the foods as they move through the supply chain.

The final rule went into effect on January 20, 2023, though all entities subject to regulation have until January 20, 2026 to comply. Because of the need for all partners to share information to achieve effective traceability, the compliance date for all parties is the same, rather than staggered as it has been for some other regulations.

Entities subject to the requirements of the final rule should speak with their supply chain partners if they haven't already. It will be important to understand existing recordkeeping systems and communication pathways to make sure the necessary data can be easily and efficiently shared, and that everyone's responsibilities along the supply chain are clear in terms of complying with the regulation.

Food allergen rules are expanded

As of January 1, 2023, the Food Allergy Safety, Treatment, Education and Research (FASTER) Act, which was signed into law in April 2021, took effect. The regulation made sesame the ninth major food allergen that companies must declare on food packaging and put in place requirements designed to increase transparency and awareness about food allergens.

The act not only imposes food labeling requirements, but also calls for preventive controls, sanitation practices and other measures to protect against cross-contamination.

According to the Associated Press, the strict requirements on manufacturers to ensure products are free from allergens, particularly sesame, is leading some companies to simply add and label the allergen. It is less burdensome than trying to adhere to the onerous processes that ensure products can be considered allergen free.

To try to help companies navigate the changes, the FDA issued a draft guidance: "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling Requirements of the Federal Food, Drug, and Cosmetic Act (Edition 5); Guidance for Industry" in November 2022. The document updates the 2006 edition and adds new information related to the labeling of food allergens, including requirements in the FASTER Act and the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).

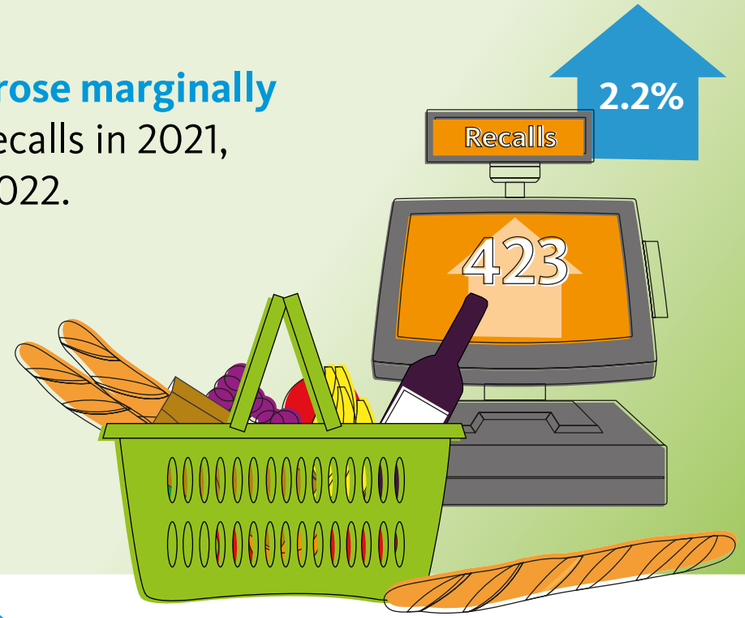
Some of the clarifications in the new guidance include the position that food in bulk containers is exempt from general mandatory food labeling requirements but must still follow guidance around major food allergens. In addition, the FDA confirms that the labeling requirements only apply to human foods. Pet foods and animal feeds, prescription or over-the-counter drugs, cosmetics, or household cleaning products are not subject to the rules.

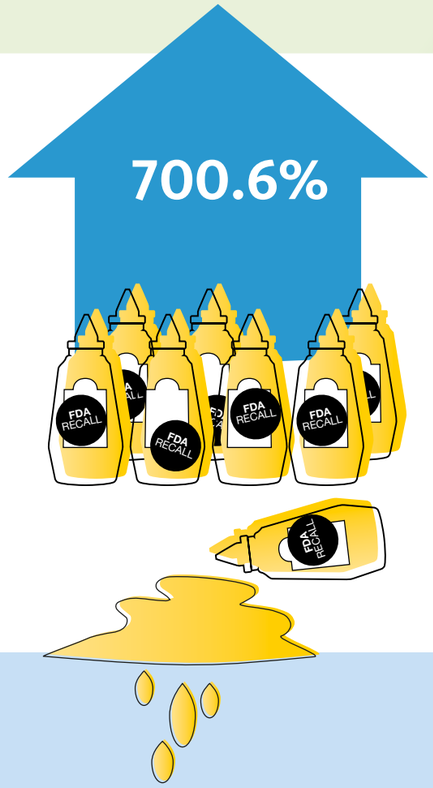
The FDA also added questions regarding dietary supplements, which had not been addressed in earlier editions. The agency confirms that dietary supplement ingredients are subject to food allergen labeling requirements and offers guidance about how and where the allergens should be declared on the dietary supplement label.

The comment period for the draft guidance closed on January 30, 2023. While guidance documents are recommendations, not regulations, companies should still review their current processes to see if they align with the agency's suggestions. If there are places that they are not in compliance, it would be wise to conduct an assessment of what it would take in terms of resources and time to make changes.

FDA food **recalls rose marginally** (2.2%) from 414 recalls in 2021, to 423 recalls in 2022.

Despite this uplift, FDA recall activity has remained constant over the last 3 years (418 in 2020, 414 in 2021, and now 423 in 2022).



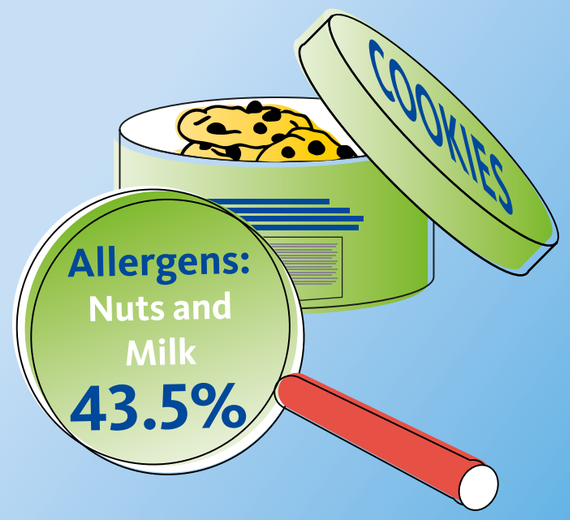


While events remained constant in 2022, **defective units surged 700.6%,** from 52.1M to 416.9M.

The combination of static events and surging units caused 2022's average recall size to inflate from 125.8K units (in 2021) to 985.7K.

At 184 events, **undeclared allergens** was the leading cause of recall in 2022 (43.5%).

Undeclared allergens has now been the leading cause of FDA recalls for 5 consecutive years.



2022 BY THE NUMBERS

FDA

The number of FDA food recalls decreased slightly from 98 in Q3 2022 to 95 in Q4. Year-over-year the number of events was relatively steady as well, with 414 in 2021 compared to 423 for all of 2022. The number of units recalled is a much different story. In 2021 there were a total of 52.08 million units of food and drink recalled by the FDA, with an average size of 125,796 units per event. Those totals increased dramatically in 2022 with 416.93 million units recalled for the year, an increase of 700.6%. The average recall size grew to 985,658 units.

From a unit perspective, the biggest risk category for Q4 FDA food recalls was contamination – other. There were 176.36 million units, or 95.9% of all units, recalled for that concern, most of which were from three events for children's supplements by the same manufacturer who was subject to the infant formula recalls in Q1. These events also made supplements the top product category by volume for food recalls in Q4.

For the eighth consecutive quarter, undeclared allergen was the top reason for recalls by event with 45, or 47.4%. Undeclared allergens has been the leading cause of FDA recall events for all but one quarter in the past five years. Despite being the leading cause for recalls, this risk was only linked to 300,000 impacted units, or 0.2% of total recalled units. It will be interesting to see how having sesame added to the list of allergens that must be declared impacts this category while companies adjust to the new regulation.

Since Q1 of 2018, Prepared foods has been the dominant product category of food recall events, including Q4 2022. There have only been five quarters since the beginning of 2018 when it has not been the leading cause. There were 25 events in the prepared food category this quarter, or 26.3% of all recalls. Baked goods and dairy products were once again tied for second, as they were in Q3, with 13 recalls. Produce was third with 12 recalls.

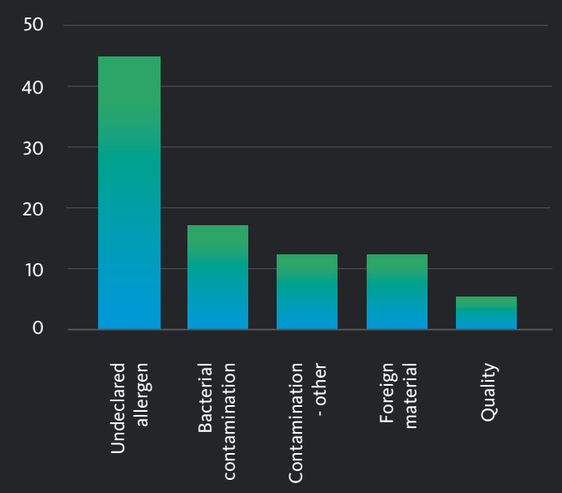
JANUARY 2023 insight

In January 2023, the FDA issued 37 food recalls. That is slightly higher than the 32 averaged per month in Q4 2022. However, the number of units recalled dropped from a monthly average of 61.33 million in Q4 2022 to 9.03 million units in January 2023, a decrease of 85.3%.

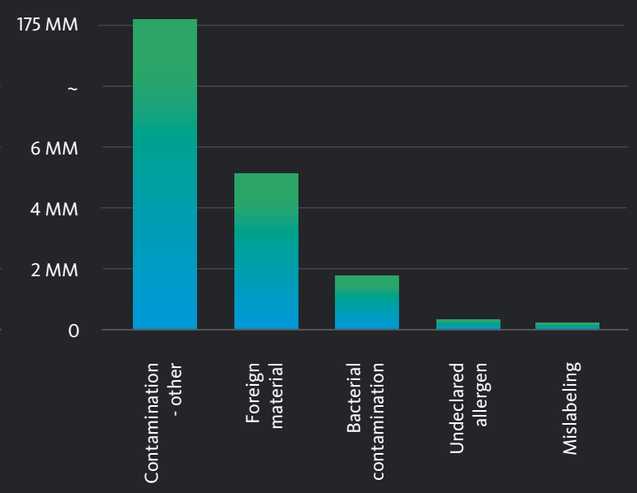
Undeclared allergens were responsible for the most food recalls in January 2023 with 16 events, though none of them were for sesame, which officially became the ninth major food allergen that companies must declare on food packaging on January 1, 2023. Bacterial contamination was the second leading cause of recalls with eight, followed by Foreign materials with four recalls.

Foreign materials were the leading cause of recalls by units with 5.92 million, accounting for 65.5% of the total number of units recalled in January. A single recall for plastic contamination in a food product accounted for 97.3% of the units recalled for this concern.

NUMBER OF FDA RECALLS BY REASON IN Q4



FDA UNITS IMPACTED BY REASON IN Q4



USDA

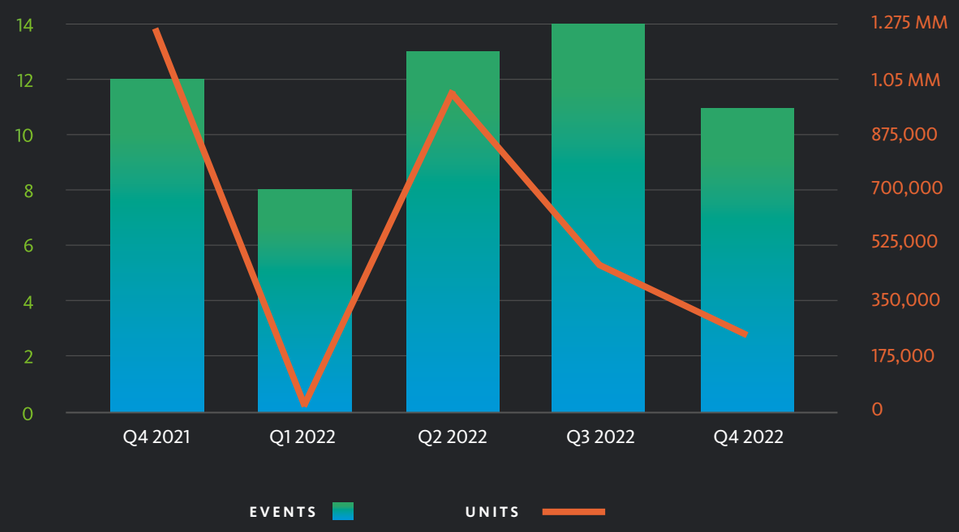
Compared to Q3 2022, the total number of USDA recalls decreased by three events to 11 in Q4. However, the number of recalls by pound dropped exponentially to 234,636, a 48.6% decrease from the previous quarter which recorded 456,828. The changes year-over-year are even more dramatic. While annual totals for recalls are almost identical, with 47 in 2021 and 46 in 2022, the number of units recalled is much different. There were 13.35 million pounds recalled in 2021 and only 1.73 million recalled in 2022. The average recall size for the year was 284,055 pounds in 2021 and only 37,611 pounds in 2022.

The top reason for USDA recalls in Q4 was foreign materials, which was linked to five events. No inspection was cited as the reason for three recalls and undeclared allergen, bacterial contamination and other contamination each had one recall.

By unit count, foreign material was also the top reason for recalls, with one recall accounting for 148,000 pounds of chicken. No inspection was second, linked to 33,911 pounds of recalled product across three different events.

Poultry was responsible for the most units recalled in Q4 by product category with 148,000 pounds. Beef was tied to five recalls, an increase from three last quarter. Multiple meats were cited for three recalls while pork had two and poultry had one. There were no seafood recalls in Q4 2022.

NUMBER OF USDA RECALLS AND IMPACTED UNITS BY QUARTER



JANUARY

2023 insight

The USDA published three recalls in January 2023, slightly down from the Q4 2022 quarterly average of four. However, in terms of units, the 2.67 million pounds that were recalled in January represent a 3313.2% increase compared to the monthly average in Q4 2022. This is largely due to a single recall of canned meat and poultry products for a packaging defect that resulted in the recall of 2.58 million pounds.

There was also a single recall due to a listeria contamination in 69,255 pounds of pork. Another recall was due to no inspection in 18,418 pounds of fully cooked and frozen Jambalaya and Gumbo products.

BY SONIA NATH, PARTNER, AND
MADELON BIRD, LAW CLERK, **COOLEY LLP**

OVERVIEW OF FDA FOOD RECALLS

Ensuring the safety of the nation's food supply is one part of the Food and Drug Administration's (FDA's) broad regulatory authority. In 2021, agriculture, food, and related industries contributed roughly $1.264 trillion, or 5.4%, to the U.S. gross domestic product (GDP) according to the U.S. Department of Agriculture (USDA).

Under the Federal Food, Drug, & Cosmetic Act (FDCA), "food" not only includes conventional food products, like fresh produce, cereals, and other packaged goods, but also beverages and dietary supplements. If the FDA determines a food poses a risk to the public, it has the authority to issue a recall.

Eggs, meat, and poultry are not regulated under the FD&C Act. The USDA oversees the recall of these products through its Food Safety and Inspection Service (FSIS).

Types of food recalls

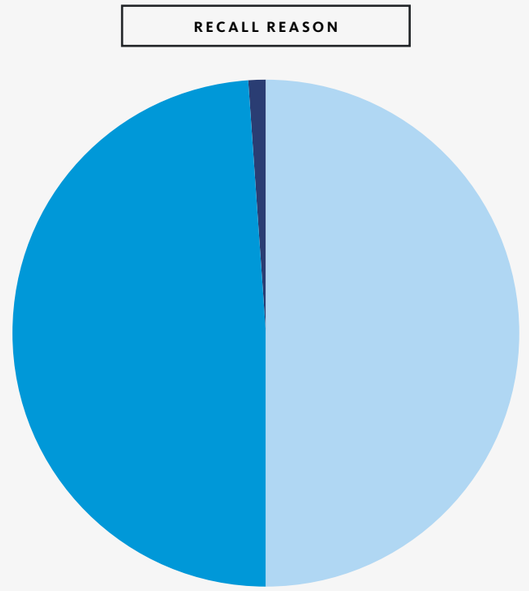
The two most common reasons the FDA issues a food recall are if the product is determined to be adulterated or if it is mislabeled (aka "misbranded"). The Food Safety and Modernization Act (FSMA) amended the FD&C Act to designate two categories of food recalls. The first is a voluntary recall, which includes recalls performed at the FDA's request. A company may voluntarily recall a violative product to remove it from the market. The second type of recall is one that is mandated by the FDA. A mandatory recall is required if two conditions are met: (1) there is a reasonable probability the food product is adulterated or misbranded because it fails to list a major food allergen; and (2) the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

Before mandating a recall, the FDA must provide the responsible party with an opportunity to voluntarily cease distribution and recall the product on its own. If the company refuses to comply with the request in a timely manner, the FDA may order the company to cease distributing the food, which may eventually result in the FDA seizing the product or taking another enforcement action, up to and including criminal prosecution.

When is food considered adulterated?

The FDA may consider a food adulterated if there is some type of contamination including bacterial, chemical, or the presence of foreign materials such as metal or lead. Food is also considered adulterated if it has been prepared, packed, or held under insanitary conditions that may have been rendered injurious to health.

Under the FDCA, dietary supplements are regulated as a subset of food. Thus, a dietary supplement containing an unsafe or new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury or a dietary supplement that is not made in conformance with current good manufacturing practice is considered adulterated and may also be the subject of a recall to protect public health or safety.



High-profile recalls for Cronobacter *sakazakii* contamination

Examples of food products recalled due to adulteration are the high-profile recalls of powdered infant formula that were contaminated with the bacterium *Cronobacter sakazakii* in 2022. In February, a major manufacturer recalled its products after receiving numerous consumer complaints of bacterial infections in infants who consumed the company's formula.

The FDA considers *Cronobacter sakazakii* an organism of foodborne illness significance for infants and children under 12 months old. In this age group, the pathogen can cause sepsis or meningitis, which may cause the infant to develop seizures, brain abscesses or infarcts, hydrocephalus, or other serious complications that can cause long-term neurological problems or even death.

On the heels of the infant formula recall, another manufacturer voluntarily recalled certain nutritional and beverage products in July 2022 due to the potential for microbial contamination, including from the organisms *Cronobacter sakazakii* and *Clostridium botulinum*. Significantly, the list of recalled products did not specifically include products intended for infants or children under the age of 12 months. The FDA's public notice about the recall stated that "while infection related to *Cronobacter sakazakii* is rare…vulnerable and immunocompromised populations may be more susceptible to infection."

Other dried food ingredients such as powdered milk, herbal teas, and starches are at high risk of contamination with *Cronobacter sakazakii*, but are typically not consumed by infants.

Most often, the bacteria is only considered an organism of foodborne illness significance in foods that are consumed by infants. However, its presence in food products is something that manufacturers should watch out for, given the recent high profile recalls. People may be averse to eating foods contaminated with the bacteria even if it doesn't pose a risk.

What is a misbranded food?

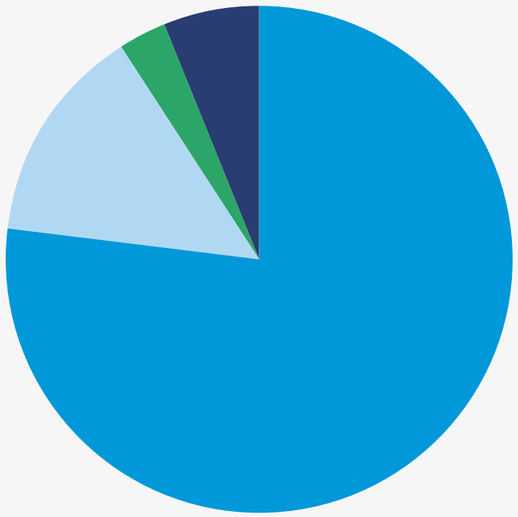
Omitting the presence of a major food allergen is one common example of misbranding. Under the FDCA, companies must declare all major food allergens on the product label, either in the ingredients list or immediately after the ingredients in a "contains" statement. This list had included only eight major allergens: milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. As of January 1, 2023, companies must also declare sesame as an allergen on food labels, including dietary supplements.

It is important to note that the law establishing labeling for sesame gives companies some breathing room. Food products that were already on their way to the store or on the shelf before 2023 are not required to relabel products or to declare sesame as an allergen. This includes products with a long shelf-life, such as canned goods. However, all products introduced into the market after January 1, 2023 must declare sesame on the label or companies can risk recall enforcement action from the FDA. This is worth highlighting given that more than 90% of all FDA food mislabeling recalls in 2022 were due to an undeclared major food allergen.

BY SONIA NATH, PARTNER, AND
MADELON BIRD, LAW CLERK, **COOLEY LLP**
CONTINUED FROM PREVIOUS PAGE

In addition to not declaring a major allergen, a food may also be considered misbranded if the label is "false and misleading." This may include claims related to the health benefits of the food that are not otherwise permitted under the FDCA, or any labeling claims that are "deceptively misdescriptive."

MISBRANDING-RELATED ISSUES



Food recalls in 2022

There were over 400 FDA recalls for food and food products in 2022. Almost all recalls were for food, not dietary supplements (92.5% vs. 7.5%, respectively), and the recalls were nearly evenly split between recalls due to adulteration and misbranding. The vast majority of the misbranding recalls were a result of food product labels that failed to declare a major food allergen.

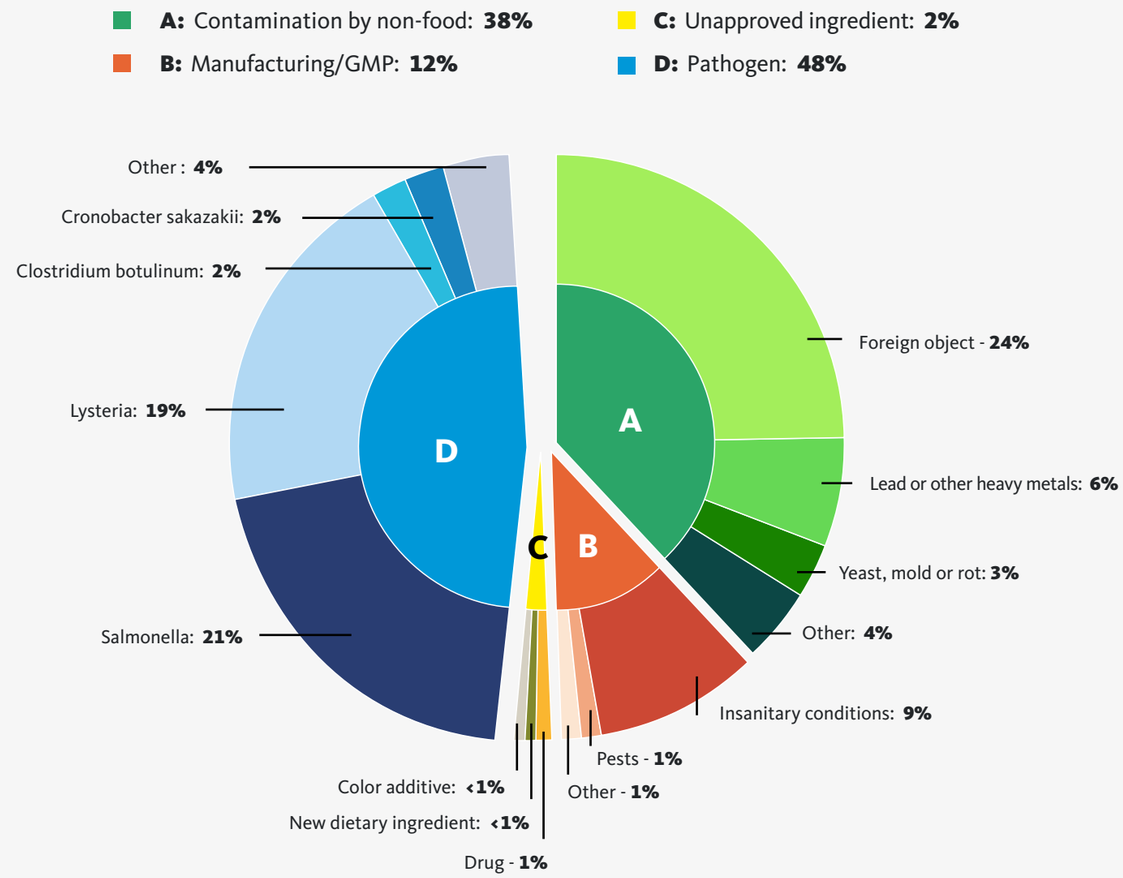
Adulteration violations most often occurred due to contamination. Common pathogens include Listeria Monocytogenes, Salmonella, and Cronobacter sakazakii; common contaminants were lead and other foreign objects, such as plastic and metal.

The year ahead

After receiving harsh criticism for its handling of the infant formula recall, the FDA is looking to revise its organizational structure. An independent evaluation of the FDA's Human Foods Program (HFP) also urged the agency to make bolder, more frequent use of its existing powers including using its mandatory recall authority. Food producers, retailers, suppliers, and distributors will need to determine the impact any internal FDA changes might have on how food safety is protected and what additional obligations they may have.

Now is also a good time for companies to review and test their recall plans to ensure that if there is an incident, they are prepared.

ADULTERATION-RELATED RECALLS



MEDICAL DEVICE

Medical device manufacturers should be on notice. As of October 1, 2023, the U.S. Food and Drug Administration (FDA) will require all medical device 510(k) submissions to use the FDA's electronic Submission Template And Resource (eSTAR) format.

A 510(k) is a premarket submission made to the FDA to demonstrate that a medical device that will be marketed in the U.S. is as safe and effective and "substantially equivalent" to a legally marketed device, as defined in the Federal Food, Drug & Cosmetics Act (FD&C Act).

As laid out in its final guidance "Electronic Submission Template for Medical Device 510(k) Submissions," original 510(k) submissions for traditional, special and abbreviated 510(k)s as well as subsequent supplements and amendments will need to be submitted to the agency electronically using the pre-specified format.

Another change for medical device manufacturers relates to mandates in the Consolidated Appropriations Act that require they submit plans for monitoring, identifying and addressing cybersecurity vulnerability once products are on the market. Previously, while the FDA had made recommendations regarding the need for device manufacturers to mitigate cybersecurity risk, there were no enforceable rules.

A collaboration between the FDA and the Veterans Health Administration (VHA), as well as an updated guidance to improve access to "breakthrough devices", are two actions the agency took in the fourth quarter to help ensure vulnerable populations or those with health disparities can get the care they need, including innovative treatments.

The FDA continues to look for ways to adapt policies and guidelines to reflect lessons learned from the ongoing COVID-19 pandemic. It updated labeling requirements for some COVID-19 tests being marketed under emergency use authorizations (EUAs). The agency also made changes to the claims that can be used to promote some COVID-19 therapeutics brought to market under EUAs.

> *"Medical device manufacturers must guarantee that their devices and associated systems are secure and commit to releasing post-market software and firmware updates and patches throughout the lifecycle of the device to maintain this assurance."*

New Mandates for Device Cybersecurity

While previously the FDA had no express federal statutory requirements for medical device manufacturers regarding cybersecurity, that changed in December 2022 with the signing of the Consolidated Appropriations Act, 2023 (H.R. 2617). The omnibus appropriations bill includes mandates for medical device manufacturers to submit plans to the FDA detailing how they will monitor, identify and address post-market cybersecurity vulnerability and exploits, including coordinated vulnerability procedures. In addition, they must supply the agency with a software bill of materials that includes all off-the-shelf, open-source and critical components used by their devices.

Under the new bill, medical device manufacturers must also guarantee that their devices and associated systems are secure and commit to releasing post-market software and firmware updates and patches throughout the lifecycle of the device to maintain this assurance.

There are also requirements for the FDA. The agency must provide information on improving the cybersecurity of medical devices within 180 days and annually thereafter. Part of the mandate includes offering guidance on how to identify and address cyber vulnerabilities for healthcare providers, health systems and device manufacturers.

To offer medical device companies more actionable steps to reduce and manage cybersecurity risks, the FDA released an updated version of the "Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook" developed in conjunction with a leading not-for-profit organization that operates federally-funded research and development centers for cybersecurity and other areas. The document offers hospitals and other health delivery organizations (HDOs) specific strategies and resources to respond to cyber incidents while ensuring medical device security.

The playbook provides recommendations for developing a cybersecurity preparedness and response framework that goes beyond existing emergency management and/or incident response capabilities. The document is designed for managing a specific medical device incident.

There are four phases to the incident response approach: Preparation; Detection and Analysis; Containment, Eradication and Recovery; and Post-Activity. There are recommendations for actions the HDO can take in each phase including analyzing hazard vulnerabilities, conducting training, categorizing and prioritizing the incident to determine the appropriate level of response, implementing a "monitor and record" strategy, and identifying what did and did not go well during the incident response process.

Some of the suggestions highlighted by legal experts at Day Pitney include knowing your regional partners and developing mutual aid agreements. Ways partners could work together include allowing patients from the impacted facility to be diverted to another HDO with operational devices or loaning the compromised facility devices to use. Another action they cited was to include cybersecurity incident response as a standard part of the procurement process. This could include securing a commitment from the device manufacturer to participate in cybersecurity exercises and training, defining the roles and responsibilities of each party and building the cost for mitigating device vulnerabilities into the device purchase and/or maintenance fees.

The attorneys also called out the importance of maintaining a centrally managed, baseline set of information about all medical devices that would include each product's operational status, location, network information and more.

While the playbook focuses on HDOs, medical device companies and distributors should pay close attention to see what risks they may have and where healthcare providers may ask for more participation from them to keep consumers and health data protected.

Push to make “breakthrough devices” more accessible to vulnerable patients

The FDA introduced the “breakthrough device” designation in 2015. Its Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Combination products are therapeutic and diagnostic products that combine drugs, devices and/or biological products.

The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment and review, while still preserving the statutory standards for premarket approval, 510(k) clearance and De Novo marketing authorization as required by the FDA.

By September 30, 2022, the FDA had granted 728 Breakthrough Device designations. However, there was a sense that not all patients had equal access to these types of treatments. In October 2022, the agency issued a draft guidance, “Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Health Care,” that proposes changes to clarify how the program may be applicable to certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions in populations impacted by health and/or health care disparities. Until the latest draft document is finalized, a 2018 edition of the program guidance will remain in effect.

In another step to help patients with complex medical issues access the best treatments, the FDA and the Veterans Health Administration (VHA) announced a collaboration to accelerate American medical device innovation. The Department of Veteran Affairs’ VA Ventures Innovation Institute will host up to 12 FDA staff to foster greater cooperation and understanding between the two agencies. The focus for the FDA will be on regulatory science around evaluating the benefits and risks of new products. The VA staff will offer clinical context for test development and provide hands-on training and other immersive experiences for innovators.

Medical device manufacturers who believe their products would fit with either program should review the latest guidance on breakthrough devices and consider reaching out to the VHA.

> *“By September 30, 2022, the FDA had granted 728 Breakthrough Device designations. However, there was a sense that not all patients had equal access to these types of treatments.”*

FDA updates EUA labeling and advertising rules

In November 2022, the FDA updated its Emergency Use Authorization (EUA) labeling requirements for all currently authorized SARS-CoV-2 antigen tests that offer repeat or serial testing. Test developers are required to submit a supplemental EUA request to the FDA with updated labeling to reflect the revised authorized uses.

The new labeling is in response to data about the performance of COVID-19 antigen tests. The research shows that repeat testing after a negative COVID-19 antigen test result increases the chance of an accurate result.

The agency wants to instruct symptomatic individuals who get a negative test result to test at least twice over three days with at least 48 hours between tests. Asymptomatic individuals who get a negative result should test at least three times over five days with at least 48 hours between tests. Test makers must implement labeling changes that reflect these new findings.

Labeling is not the only aspect of COVID-19 therapeutics that is changing. In October 2022 the FDA announced that it will now permit certain COVID-19 drugs that have been granted EUA to make safety and efficacy claims in print, advertising and promotional materials, within certain parameters.

While medical products that receive EUA still must undergo a review process with the FDA, the requirements for obtaining EUAs are less burdensome than the requirements for obtaining full FDA approval. That lower evidentiary threshold for EUA comes with a number of conditions to protect the public, since the medical product has not been evaluated as fully.

Those conditions often include limits to the promotional claims that can be made about the product, among other restrictions. According to legal experts at Sheppard Mullin, since the beginning of the COVID-19 emergency, the FDA's Center for Drug Evaluation and Research (CDER) has prohibited developers of COVID-19 drugs from representing or suggesting that a COVID-19 drug is "safe" or "effective" for its authorized use in any print, advertising or promotional materials.

However, in its October memo, the CDER acknowledged that with the changing epidemiological landscape and shifting infection rates for COVID-19, it is important to make accurate and non-misleading information on the authorized COVID-19 therapeutics available to advance the public health. The agency revised its policy to allow companies to make certain claims related to safety or efficacy if those claims are tied to clinical trial results. Manufacturers are still expressly prohibited from implying that their products are FDA approved or that they are "safe" or "effective" for the authorized use.

In addition, any print, advertising and promotional materials for these COVID-19 therapeutics must be submitted to the FDA at least 14 days before they are first used or disseminated.

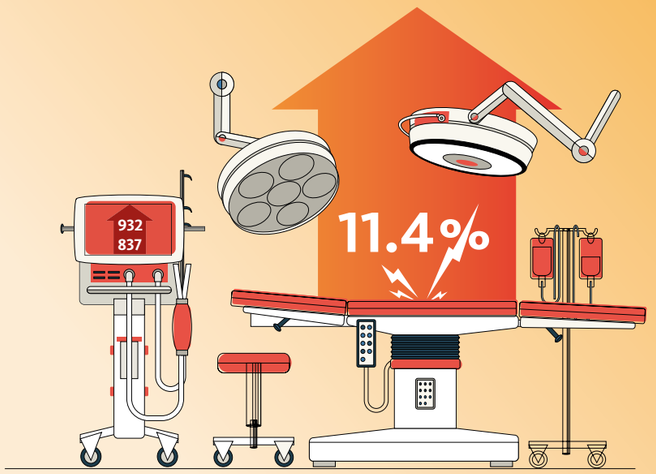
While the CDER defines "COVID-19 therapeutics" as drugs in the memo, medical device manufacturers should monitor the agency's announcements. With the public health emergency still ongoing, there would be an advantage to COVID-19 at-home test companies if they could make similar efficacy claims.

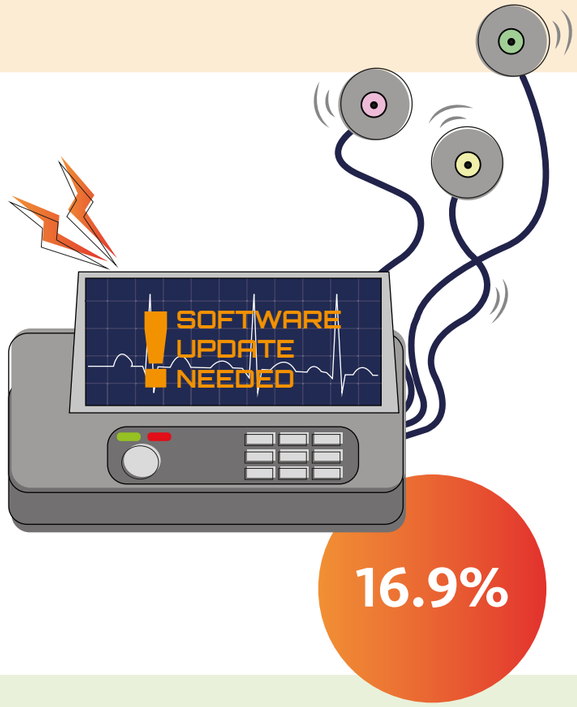
In addition, the lawyers with Sheppard Mullin note that if the FDA extends these guidelines around promotion to other EUA drugs, other drug developers pursuing candidate products would benefit from being able to more widely discuss their therapeutics.

> *"The CDER acknowledged that with the changing epidemiological landscape and shifting infection rates for COVID-19, it is important to make accurate and non-misleading information on the authorized COVID-19 therapeutics available to advance the public health."*

Medical device **recall events increased** 11.4% in 2022, from 837 (in 2021) to 932.

There were 70 Class I designated events, representing a 15-year high. For context, the last 5 years have recorded an average of 47 Class I designations annually.



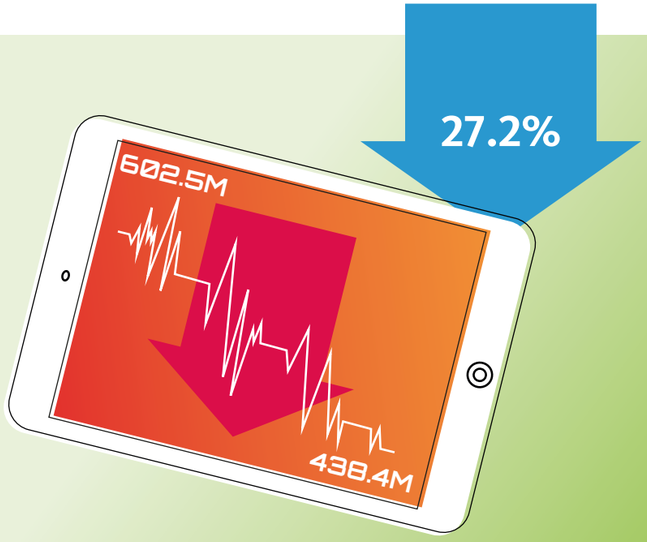


Accounting for 154 events (16.9%), **Mislabeling was the leading cause of recall** activity in 2022.

This supplanted Software, which held the top position for 5 consecutive years (2017 to 2021).

While recall events increased, the number of **defective devices fell** 27.2%, from 602.5M in 2021, to 438.4M.

The combination of increasing events and declining units caused 2022's average recall size to contract from 719.8K units (in 2021) to 470.4K.



2022 BY THE NUMBERS

Year-over-year, the total number of medical device recalls increased by 8.8%, going from 837 in 2021 to 911 in 2022. There was also an increase between Q3 and Q4 2022, though only 8.1%. In a change from the normal recall trends, the number of units impacted for the year significantly decreased from 602.51 million in 2021 to 438.37 million in 2022. While this was a 27.2% drop from the previous year, it was on par with total units for 2018 – 2020. Comparing Q3 and Q4, the number of impacted units increased slightly from 51.48 million in Q3 to 61.98 million units in Q4 2022, making it the second-highest quarter for the year.

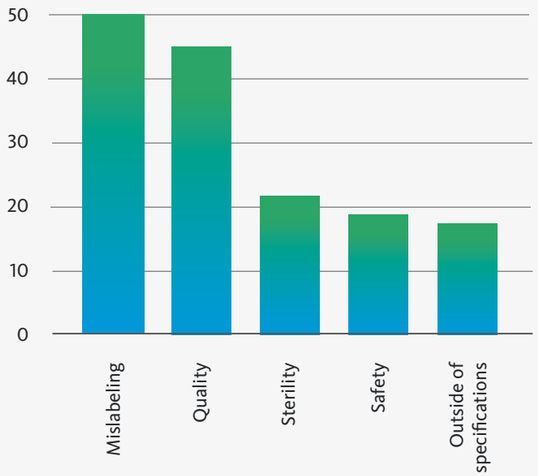
Mislabeling was the leading cause of recalls in the fourth quarter of 2022, as it has been for the last three out of five quarters, including Q4 2021. The 50 events attributed to mislabeling accounted for 20.7% of Q4 recalls. Quality was the second most common reason for recalls at 46 events. Unlike past quarters, software only had 15 events in Q4 compared to 45 in Q3 when it was the leading cause of events.

Leakage was the top cause for recalls in terms of units impacted, accounting for 27.17 million units, or 43.8% of all units in Q4 2022. Quality was the second most common cause with 10.74 million (or 17.3%), followed by safety concerns with 7.89 million units (or 12.7%).

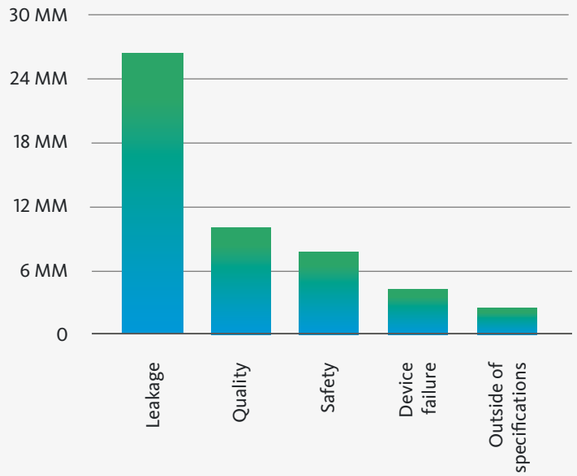
There were five recalls for COVID-19 at-home tests and testing products for a range of concerns including lack of authorization, false results and mislabeling. The recalls impacted 1.02 million units.

Eighteen events (7.5%) in Q4 were labeled with the FDA's most serious Class I designation. These recalls impacted 3.02 million units. Class II recalls accounted for the largest percentage of recalls at 216 events (89.6%) and the largest number of units at 58.95 million. The remaining seven recalls in Q4, which involved 12,410 units, were designated as Class III.

NUMBER OF FDA RECALLS BY REASON IN Q4



NUMBER OF UNITS IMPACTED BY REASON IN Q4



JANUARY

2023 insight

There were 135 recalls for medical devices in January 2023, significantly higher than the monthly average of 80 in Q4 2022. The number of units also increased with 69.88 million units recalled in January compared to the monthly average of 20.66 million in the last quarter of 2022. This represents an increase of 238.2%.

Manufacturing defects were the most common reason cited by the FDA for medical device recalls in January 2023, accounting for 47 events, or roughly 34.8% of the total. Sterility was second with 20 recalls. While quality was the third-highest category in terms of events with 16 recalls, it accounted for the most units impacted. There were 68.48 million units recalled for quality in January 2023. Most of them were tied to a single recall of 66.45 million infusion system sets.

There were three recalls for rapid COVID-19 tests or testing components in January 2023. One was flagged due to no emergency use authorization, another for false results, and the third for leakage. Combined they accounted for 67,494 units.

SONIA NATH, PARTNER, AND **JAMES WYATT KERNELL,** ASSOCIATE, **COOLEY LLP**

FDA'S APPROACH TO MEDICAL DEVICE RECALLS IN THE U.S.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) gives the U.S. Food and Drug Administration (FDA) wide latitude to regulate medical devices, including the authority to mandate product recalls in certain situations.

Typically, medical device manufacturers voluntarily recall products. However, if a manufacturer fails to conduct a voluntary recall, a product that the FDA determines is a risk to health and where there is a "reasonable probability that a device intended for human use would cause serious, adverse health consequences or death," the agency may issue a mandatory recall order to the manufacturer, importer, distributor, or retailer of the device. In this case, the relevant entity would be ordered to immediately cease distribution and to "immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device."

Despite having this power, the FDA has only mandated a medical device recall a handful of times. This is due in large part to manufacturers voluntarily initiating recalls. The agency also has other enforcement tools it can use such as seeking injunctions, seizures, and civil money penalties. The FDA is also authorized to mandate certain notifications necessary to eliminate the unreasonable risk of substantial harm to the public health. This includes ordering the manufacturer, importer, or any distributor of such device to repair, replace, or issue a refund for the device in question.

FDA flexes its authority in 2022

In 2022 alone, the FDA reported more than 900 medical device recalls. However, one of the most significant developments in medical device recalls involved the agency's recent use of one of its Section 518 authorities, which is a power it has generally not relied on.

Section 518 of the FD&C Act is designed to protect public health by offering the FDA a way to assure hazardous products that are in the market are repaired, replaced, or refunded. It also establishes a procedure for impacted consumers to receive economic redress if they have been sold defective medical devices that present unreasonable risks.

In June 2021, there was a Class I recall by a major medical device manufacturer for certain ventilators and continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines because the degradation of the polyester-based polyurethane (PE-PUR) sound abatement foam used in those products presented a health risk to device users. The FDA received reports of problems and concerns with the recalled products from individuals who were unaware that the recall had taken place.

The agency monitored the company's recall, including contacting a sample of 182 consignees to determine whether they had been notified of the recall. Of those contacted, 23 were unaware of the recall. This fact, along with other issues with the manufacturer's notification to consignees, led the FDA to issue a Section 518(a) order to the company requiring it to notify all health professionals who prescribe or use the recalled products of the recall and the health risks presented by the recalled products within 45 days.

The FDA was very prescriptive in its order and required the device manufacturer to take a number of additional steps to ensure all patients were made aware of the recall. The company was also mandated to keep the FDA informed of the progress and plan for implementation.

The agency followed this Section 518(a) order with a Section 518(b) order requiring the manufacturer to submit a plan for the repair, replacement, and/or refund of the purchase price of devices subject to the recall that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial harm to the public health presented by those devices will be eliminated. In accordance with section 518(b), the FDA also afforded the company an opportunity for an informal hearing under FDA regulations.

The FDA's actions against the medical device manufacturer is a reminder that if companies are not thoughtful and thorough when executing a recall, particularly a Class I recall, the FDA may step in to protect the public's health. As the agency often reminds us, at its core, it is a public health agency.

Software as a medical device recalls

The FDA has increasingly focused on Software as a medical Device (SaMD) in the past few years. In 2013, the International Medical Device Regulators Forum, a voluntary group of medical device regulators from around the world, formed the Software as a Medical Device Working Group, led by the FDA. This working group defined SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device."

Thereafter, in 2016, Congress passed the 21st Century Cures Act (Cures Act) that provided greater detail on the FDA's authority to regulate software as a medical device. In response, the agency has been hard at work generating guidance documents to outline its perspective on the new law. In the past year alone, it has issued several revised and final guidance documents on topics related to SaMD, including guidance documents on clinical decision support software, mobile medical applications, medical device data systems, and cybersecurity in medical devices. Many of these guidance documents, including the guidance on clinical decision support software, appear to tighten the Cures Act-enumerated exceptions for software falling outside the classification of a medical device.

In 2022, while not widely publicized, there were roughly 50 recalls that related to SaMD. These recalls ranged from software issues that would result in inadvertent muting of patient care alarms to SaMD losing patient data to errors involved in surgical procedures. With the influx of software-based medical care and the FDA's increased attention on SaMD, it is perhaps surprising that the percentage of recalls associated with SaMD in 2022 was relatively small when compared to the number of device recalls generally reported by FDA. In 2022, they made up roughly three percent of all medical device recalls.

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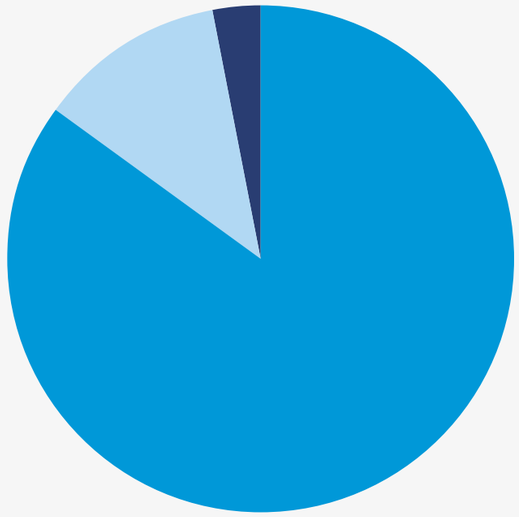
PROPORTION OF 2022 MEDICAL DEVICE RECALLS THAT INVOLVED SOFTWARE VS SaMD



There are at least three reasons that can explain this low percentage. First, while its prevalence is increasing, software as a medical device is far from the norm and many devices on the market today do not use software either in or as a device.

Second, depending on the functionality of the SaMD, an issue with the software could range from low-risk issues that result in a Class III recall for which there is no mandatory reporting to FDA. For example, in a review of the FDA's medical device recall data, we identified only one Class I recall for SaMD, which resulted from a risk of potential miscalculations that could result in medication errors. As this type of software becomes increasingly popular and included in more modern and recently approved and cleared devices, we anticipate seeing more such recalls in the future. Relatedly, issues with SaMD may not be considered recalls as software enhancements are routinely provided and pushed out remotely to devices.

Third, it is possible that players in the SaMD market may be software developers or emerging companies that are not accustomed to being regulated by the FDA and therefore not familiar with the rules and regulations regarding recalls. Thus, when these companies detect issues with their applications, they may update them as they do any other software, without understanding that the FDA may need to be notified for updates that pose risk to human health or are otherwise violative of the FD&C Act.

Finally, it is worth noting that while there were relatively few recalls in this space, there were a number of public notifications relating to cybersecurity issues. For example, one company recently issued an Urgent Medical Device Correction due to a potential cybersecurity threat that could allow unauthorized access to its insulin pumps. The FDA in turn posted a public notice of this correction on its website, on a separate webpage focused on cybersecurity. As more devices comprise or include software, we anticipate seeing more recalls and other notifications in this area as well.

In addition, the Consolidated Appropriations Act, 2023 (H.R. 2617), which was signed in December 2022, includes mandates for medical device manufacturers to submit plans detailing how they will monitor, identify and address post-market cybersecurity vulnerability and exploits, including coordinated vulnerability procedures to the FDA. This is the first time that the agency has had express federal statutory requirements for medical device manufacturers regarding cybersecurity.

Looking ahead

Moving into 2023, medical device companies, distributors, and suppliers will need to plan for increased oversight from the FDA in terms of SaMD. They should also expect the agency to continue to use all of its enforcement power to protect public health, which means companies should ensure their recall plans and protocols include proper notification and redress for consumers.

PHARMACEUTICAL

The Biden Administration ended 2022 with major changes that will have big impacts across the pharmaceutical sector. On December 29, 2022, President Biden signed the Consolidated Appropriations Act, 2023 (H.R. 2617), an omnibus appropriations bill to fund the U.S. government for fiscal year 2023. Included among the more than 4,000 pages of the bill were a series of reforms relevant to the pharmaceutical industry including the Food and Drug Omnibus Reform Act of 2022 (FDORA) and the Modernization of Cosmetics Regulation Act of 2022 (MOCRA). Both acts have numerous new obligations for manufacturers and other stakeholders around issues such as marketing, clinical trials and the U.S. Food and Drug Administration's (FDA's) authority.

The FDA is not the only agency making waves across the pharmaceutical industry. The Federal Trade Commission (FTC) released its "Health Products Compliance Guidance" in December. This is the first update in 25 years and the guidelines have expanded to include not only dietary supplements but anything deemed a "health product," which can include foods, over-the-counter drugs, homeopathic products, health equipment, diagnostic tests and health apps.

The guidance also specifies enforcement actions the FTC can take which can include banning a company from engaging in certain marketing activities, consumer refunds or civil penalties.

In the first week of January 2023, the Biden Administration belatedly released the Fall 2022 Unified Agenda of Regulatory and Deregulatory Actions (the Unified Agenda) which includes information from federal agencies regarding their planned short- and long-term rulemaking actions and gives companies insights into the agencies' priorities for the year ahead.

The latest Unified Agenda lists 74 short-term actions, including 47 proposed rulemakings and 27 final rulemakings, and 13 long-term actions for the FDA. These activities fall across all FDA-regulated product categories, including drugs, biologics, medical devices, conventional foods, dietary supplements, animal products, cosmetics, tobacco products and radiation-emitting electronic products. While this list is often aspirational, companies should still review the agenda to help plan for any changes.

> *"Because of the wide scope and the number of reforms included in the FDORA, it is likely that most pharmaceutical companies and other stakeholders will need to change some of their processes – whether it is record-keeping or clinical trials."*

The Food and Drug Omnibus Reform Act has wide-ranging effects for the pharmaceutical industry

The Food and Drug Omnibus Reform Act of 2022 (FDORA), which was included as part of the omnibus appropriations bill, includes several provisions expected to be part of the FDA's user fee reauthorization process. However, lack of agreement in Congress and negotiating right up to the deadline resulted in the user fee reauthorization being passed just before it expired, but without any of the typical policy riders.

Among the key reforms in the FDORA are provisions to promote diversity in clinical trials, including the need to submit "diversity action plans" for certain late-stage drug trials, numerous changes to the accelerated approval process for drugs and biologics, clarification that certain products such as contrast agents, radioactive drugs, or over-the-counter monograph drugs are to be classified as drugs and not devices, as well as changes to the licensing and marketing of biologics.

The omnibus bill also amends section 505 of the Federal Food, Drug & Cosmetic Act (FD&C Act) to allow clinical sponsors to use computer modeling or other non-animal testing and still fully meet the FD&C Act's required demonstrations of efficacy and/or safety. Other amendments to the Public Health Service Act allow sponsors to conduct non-animal biosimilar toxicity testing.

Because of the wide scope and the number of reforms included in the FDORA, it is likely that most pharmaceutical companies and other stakeholders will need to change some of their processes – whether it is record-keeping or clinical trials. For products that were previously classified as devices and are now regulated as drugs, some of the changes to internal compliance and production practices may be significant.

Many of the changes laid out in the new bill will require implementation and interpretation by FDA through regulations or guidance documents, though some go into effect immediately. Engaging with outside counsel may be helpful to review and assess the full scope of the document as quickly as possible so that companies can decide their next steps.

Federal cosmetics regulations bring risk and burden to manufacturers

The FDORA was not the only significant legislation included in the Consolidated Appropriations Act. It also authorized the long-awaited Modernization of Cosmetics Regulation Act of 2022 (MOCRA). The MOCRA amends Chapter VI of the FD&C Act and creates federal standards for cosmetic products.

Under the FD&C Act, the definition of a "cosmetic" is very broad and includes any article "intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance."

That means that the MOCRA will apply to not only traditional make-up products like eye shadow and lipstick, but also a whole range of perfumes, hair care products, deodorants and moisturizers.

These new provisions align cosmetic products more closely with other FDA-regulated products that do not require premarket approval, such as dietary supplements and over-the-counter drugs. Some of the new requirements under MOCRA include adhering to Good Manufacturing Practices (GMPs), additional labeling, safety substantiation, adverse event reporting and registration and listing with the FDA. There are also regulations for allergen labeling for fragrances and methods to test for asbestos in talc-containing cosmetic products.

One of the most significant changes in the MOCRA is much stronger recall authority for the FDA when quality or safety risks are linked to a cosmetic product. If the FDA determines with reasonable probability that a cosmetic is adulterated or misbranded and that using the product will cause serious adverse health consequences or death, it now has the authority to order a recall of the product if the responsible party connected to the product will not agree to voluntarily recall the product and halt distribution.

Under the new regulations, when a cosmetic recall occurs, either voluntarily or through an FDA mandatory recall order, a press release regarding the recall must be published. In addition, the agency is required to ensure that all proper alerts and notices are issued to the public and on the FDA's website.

Furthermore, the FDA also has the authority to suspend a facility's registration under certain conditions. That would prohibit the facility from placing its products on the market in the U.S.

Attorneys with Greenberg Traurig note that the changes to the regulatory scheme for cosmetics and new obligations facing stakeholders may also create new opportunities for plaintiffs to file personal injury, product liability and consumer litigation claims. They state that FDA reporting and manufacturing requirements "provide fertile ground in discovery to explore potential non-compliance," along with other possible claims.

As cosmetics companies work to comply with all the new regulations, they should keep in mind the risks they have as a result of these. They should consider ways to mitigate the possibility that other parties will try to take advantage of any vulnerabilities as the companies learn the new regulatory regime.

FTC updates guidelines for health product claims

In December 2022, the Federal Trade Commission (FTC) issued its "Health Products Compliance Guidance," marking a significant update from the agency's "Dietary Supplements: An Advertising Guide For Industry," which was issued 25 years ago. The goal of the document is to provide guidance to companies so that they can ensure any claims they make about the benefits and safety of their health-related products are "truthful, not misleading, and supported by science."

While the earlier guidance only applied to dietary supplements, the new version covers any health-related product, such as foods, over-the-counter drugs, homeopathic products, health equipment, diagnostic tests and health apps. It pulls 23 real-world examples from the 200+ cases the FTC has brought since 1998 that challenged false or misleading advertising claims for health-related products.

Under the new guidelines, businesses must consider a significant number of compliance factors before publishing health product marketing. Some of these factors include the express and implied claims suggested by the ad, any prominent disclosure of qualifying information, claims based on consumer testimonials and expert endorsements and the reliance on third-party literature for substantiation.

According to the FTC, these new requirements apply to a wide range of advertising and marketing channels including statements or depictions on packaging and labeling, promotional materials such as brochures or booklets, online and digital content and social media and influencer marketing content and statements.

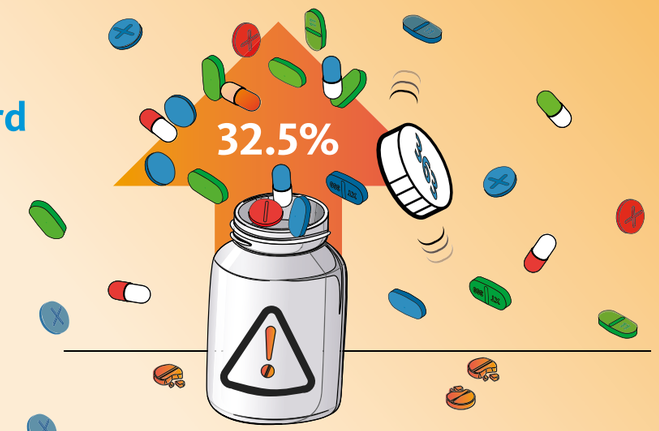
Marketers are not the only parties who are potentially liable under the revised document. The FTC also states that individual owners and corporate officers of the marketer, ad agencies, distributors, retailers, catalog companies, infomercial producers and "expert endorsers" have "an obligation to make sure that claims are presented truthfully and to check the adequacy of the support for those claims."

If the FTC determines that an advertiser is making deceptive claims, it can mandate that the company cease making those statements. It also has the authority to mandate disclosures and corrective advertising, ban a company or individual from engaging in certain marketing activities altogether and seek financial remedies, which could include consumer refunds or civil penalties.

In addition to the costs of implementing any of these remedies, companies could also pay a price to their reputation and their brand if they are called out for deceptive practices. The Commission has taken an aggressive stance in filing complaints against large companies it believes has violated consumers' "right to repair." It is unclear if they will be as proactive with companies on this issue.

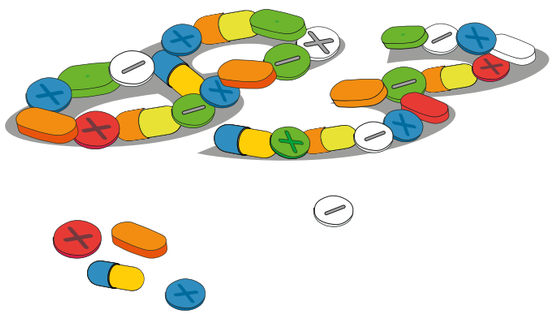
> *"Under the FTC's new guidelines, businesses must consider a number of compliance factors before publishing health product marketing, including the express and implied claims suggested, any disclosure of qualifying information, as well as claims based on consumer testimonials and expert endorsements."*

Pharmaceutical **recall events surged by a third** (32.5%), from 274 in 2021, to 363 in 2022.



Only 1 year in the last 10 has recorded more events (2018 with 376 recalls).

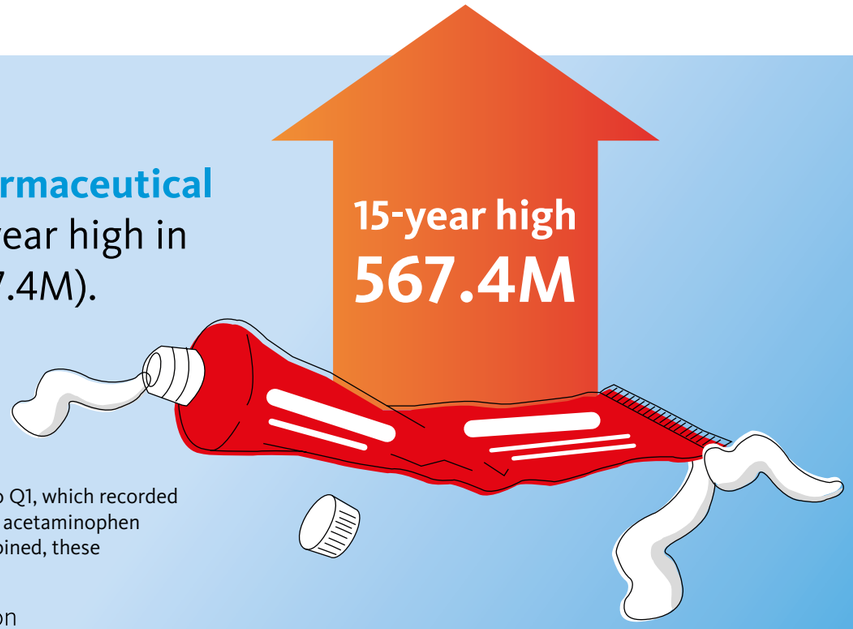
437.5M



cGMP **deviations dominated recall activity** with 83 events and 437.5M impacted units in 2022.

Only one year in the last 5 (2020) has recorded more events due to cGMP deviations (92), none have registered more units.

Defective pharmaceutical units hit a 15-year high in 2022 (with 567.4M).



This was largely attributed to Q1, which recorded 3 separate events relating to acetaminophen (for cGMP deviations). Combined, these accounted for 421.0M units.

2022 BY THE NUMBERS

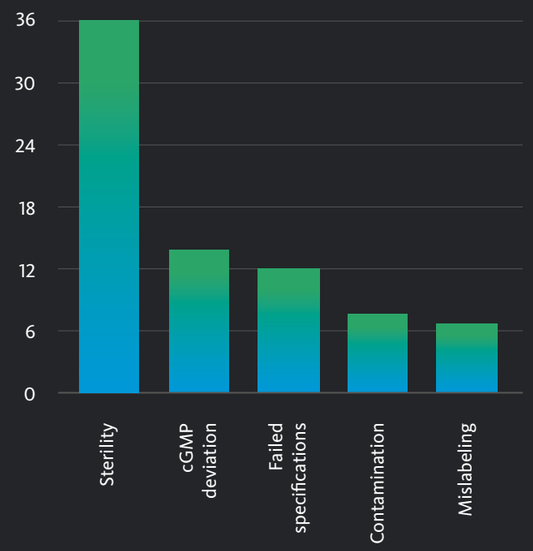
Pharmaceutical recalls increased by 16.1% in Q4 with 94 recalls compared to 81 in Q3. While the number of events went up, the number of units sharply declined to 4.2 million, 96.1% fewer than the previous quarter. This makes Q4 the lowest quarter for pharmaceutical units recalled since Q4 2017. However, because of the large recalls seen in Q1 and Q3, 2022 still had the most units recalled in the past six years with 567.3 million. That is a 114.4% increase compared to the 264.6 million units recalled in 2021.

For the first time in more than six years, sterility was the top cause of pharmaceutical recalls in terms of events with 36 recalls. The second most common reason was cGMP deviation, which was linked to 13 events in Q4, a 31.6% drop from Q3 when it was the leading concern (with 19 events). Failed specifications accounted for 12 recalls, making it the third most common cause.

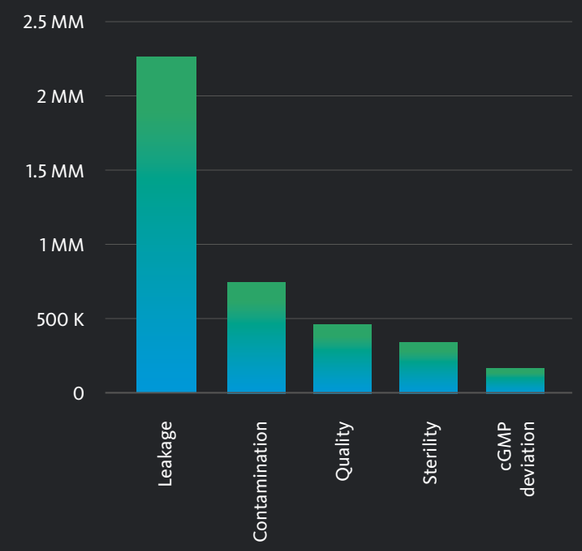
Looking at units recalled, leakage was the top reason with more than 2.27 million units recalled, or 53.7% of total units in Q4. A single recall of a defective container accounted for 2.1 million of those units. Contamination came in second with 723,423 units recalled and quality concerns were third with 422,491 units.

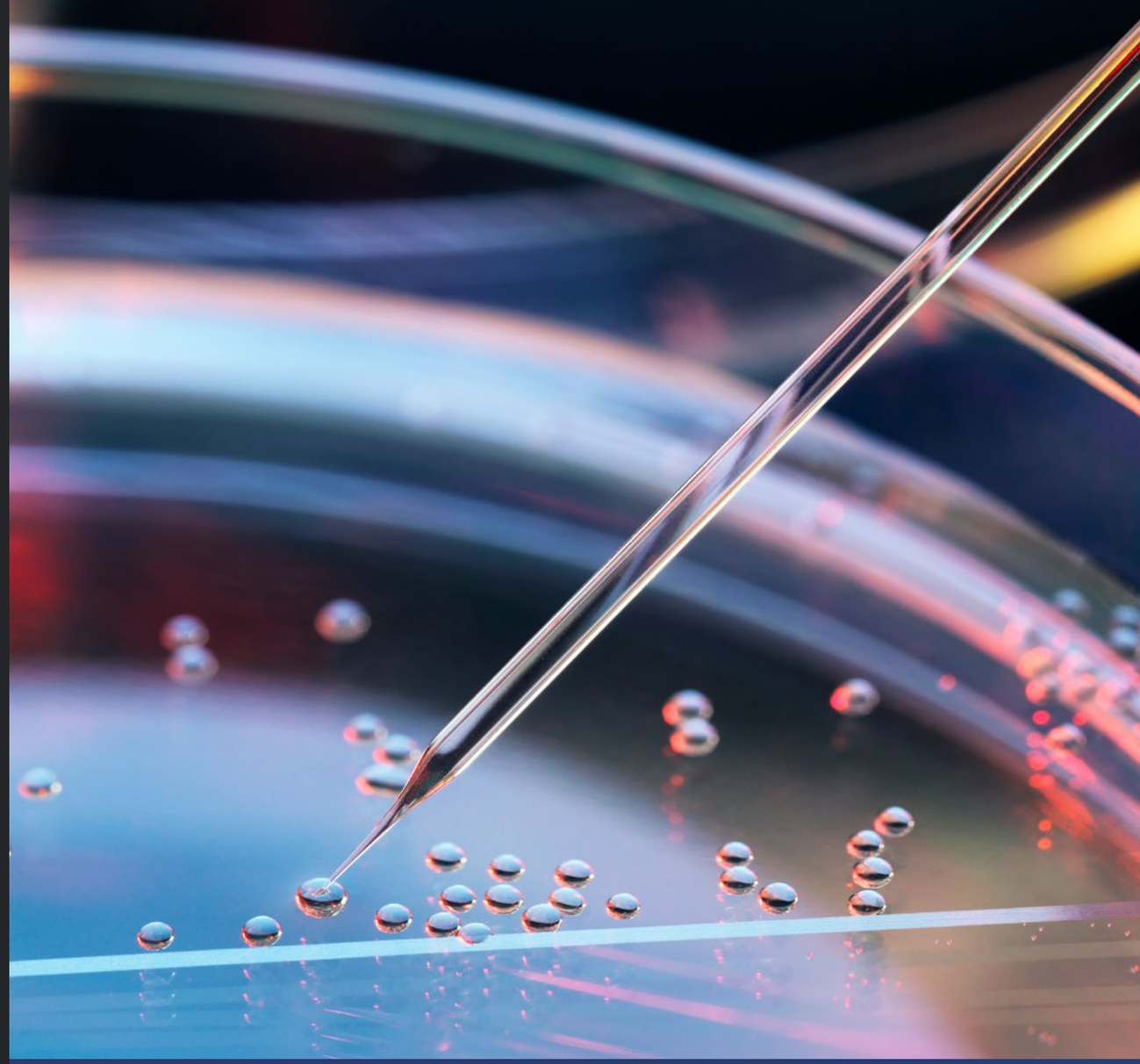
The FDA classified nine Q4 2022 recalls as Class I, which are the most serious. These recalls impacted approximately 2.8 million units, the most of any class this quarter despite being only 9.6% of all units recalled. Class II recalls accounted for 72 (76.6%) recalls impacting 1.2 million units. The remaining 13 recalls, which impacted 160,649 units, were designated as Class III.

NUMBER OF FDA RECALLS BY REASON IN Q4



NUMBER OF UNITS IMPACTED BY REASON IN Q4





JANUARY

2023 insight

The FDA reported 47 pharmaceutical recalls in January 2023. That is 51.6% higher than the Q4 2022 monthly average of 31 events. In terms of units, there was a dramatic increase with 15.45 million units recalled in January 2023. This is 996.0% higher than the Q4 2022 monthly average of 1.41 million units.

cGMP deviations were the reason for both the most recall events (13) and most units impacted (11.88 million). That is 76.9% of the total number of pharmaceutical units recalled in January 2023. Sterility concerns were the second most common reason for recalls by event with nine, followed by failed specifications with seven. Quality issues were cited in only five recalls, but recorded the second most impacted units with 1.32 million.

CONCLUSION

The November 2022 mid-term elections changed the political makeup of the U.S. Congress when the Democrats lost control of the House. With a Republican majority in the House and the Senate still controlled by Democrats, there is already a lot of partisan bickering over legislative priorities. There is not much optimism for sweeping bi-partisan changes, especially as politicians start laying the groundwork for the next presidential elections in 2024.

What does seem likely is continued robust enforcement by regulators. The CPSC started the year with a big civil penalty and the Commission is expected to pursue more fines. The FTC is also not shying away from claims against companies, and with the new changes to health product advertising, there is more risk for manufacturers, distributors and retailers.

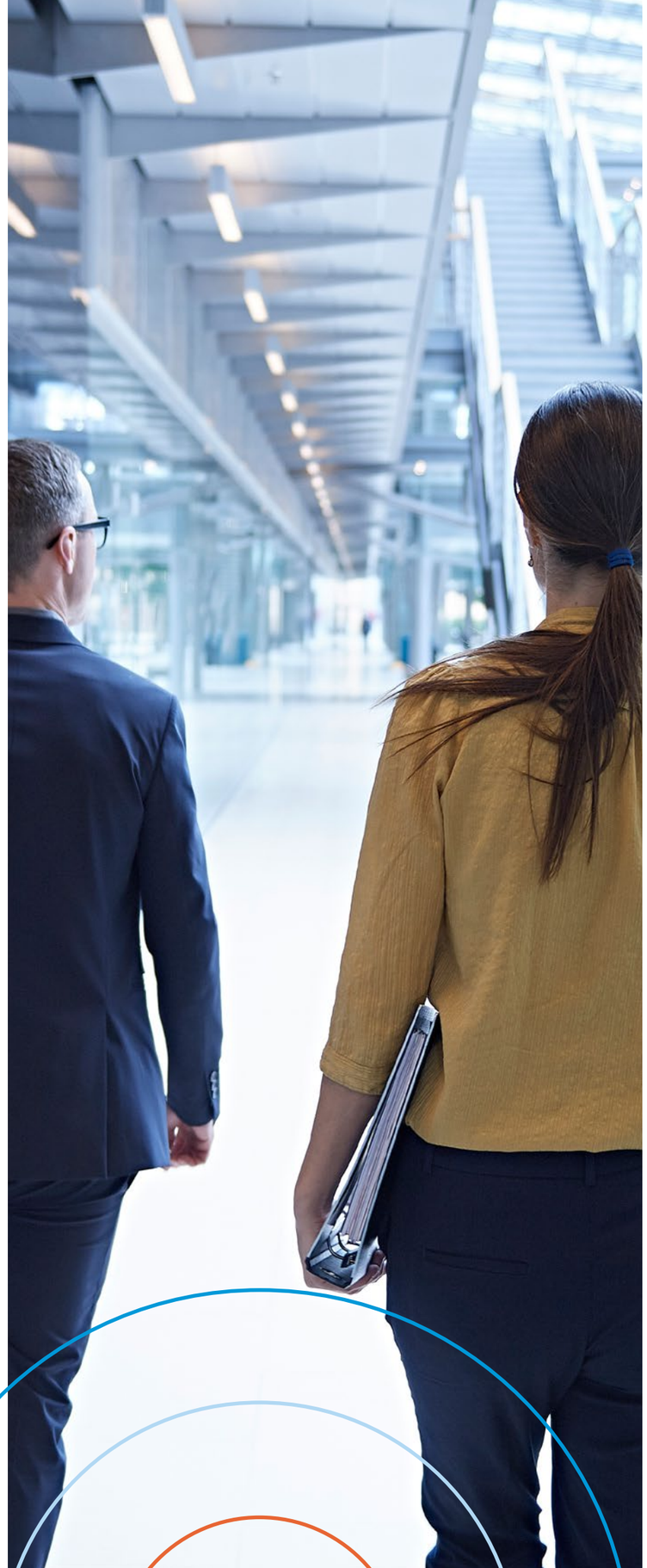
The new FDA regulations that were part of the omnibus appropriations bill also brings increased vulnerabilities for companies as they work to adapt to the new mandates across sectors.

With all the unknowns, companies will need to plan for risks across a variety of areas, including the following:

- Business interruptions
- Supply chain challenges
- Regulatory and legislative changes
- Financial impacts
- Product updates, upgrades and warranty work
- Product recalls and market withdrawals
- Data, privacy and cybersecurity issues
- Innovation and advancements in technology
- Constantly shifting consumer demand
- Customer and partner apprehension

In today's business environment, product recalls are inevitable. But if recall and remediation plans – and testing and updating of those plans – become as routine as other business processes, companies can mitigate their impact and protect their brand if the worst occurs.

Working with an expert partner to leverage their experience and insights can help to save millions of dollars in regulatory and litigation costs, as well as time and stress on other internal resources. In addition, their expertise will help you honor your commitments to customers, supply chain partners, industry groups and regulators, while protecting your reputation among the stakeholders that matter most.



ABOUT SEDGWICK BRAND PROTECTION

We are in-market risk experts. We are problem solvers. We protect businesses, their customers and our environment through best practice product recall, remediation and customer retention solutions.

Trusted by the world's leading brands and businesses, we work in partnership to manage the risks and minimize the impacts of in-market business and product crises.

When your reputation is on the line, we put our 25+ years of global experience on 5,000+ recalls affecting 500MM+ units to work for YOU. No one knows more about the recall and regulatory process than we do.

Through that lens, we've seen industries evolve based on changing legislation, advancements in technology, shifts in consumer preferences and behaviors and the growing complexities brought about by the transformation of supply chains.

We haven't just watched this evolution. We've been part of it. We've helped companies around the world prepare for and adapt during some of the most challenging events in their history.

While this Index report provides a roadmap for expected changes ahead, our experience means that there is nothing we haven't seen or dealt with before. In fact, it's often that these events, even those that feel devastating to companies experiencing them, that offer opportunities to demonstrate trustworthiness and to build greater customer loyalty when conducted well.

Sedgwick's extensive brand protection resources, combined with our unmatched experience handling thousands of recall events, give us a unique perspective on the risks, challenges and often overlooked opportunities associated with the reputational threats you face every day.

In an increasingly complex and regulated world, being prepared for risks is essential. Having the capabilities to act quickly and effectively is critical. Let us leverage our capabilities for you.

To find out more about our product recall capabilities, contact us today.

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